FUNCTIONAL OUTCOME OF NONUNION LONG BONE FRACTURE TREATMENT BY LIMB RECONSTRUCTION SYSTEM-PROSPECTIVE AND RETROSPECTIVE STUDY

Dissertation submitted for

M.S DEGREE EXAMINATION

BRANCH II-ORTHOPAEDIC SURGERY

INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY

MADRAS MEDICAL COLLEGE AND RAJIV GANDHI GOVERNMENT GENERAL HOSPITAL

CHENNAI-60003

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

CHENNAI-600032

APRIL-2014

CERTIFICATE

This is to certify that this dissertation in ***"FUNCTIONAL OUTCOME OF NONUNION LONG BONE FRACTURE TREATMENT BY LIMB RECONSTRUCTION SYSTEM-PROSPECTIVE AND RETROSPECTIVE STUDY"*** *is a bonafide work done by* **Dr.S.KARTHIKEYAN** *under my guidance during the period 2011–2014. This has been submitted in partial fulfilment of the award of M.S. Degree in Orthopedic Surgery (Branch–II) by The TamilnaduDr.M.G.R. Medical University, Chennai.*

PROFM.R.RAJASEKAR

Director, Institute of Orthopaedics and Truamatology
Madras Medical College &
Rajiv Gandhi Govt Gen. Hospital
Chennai – 3.

PROF.V.KANAGASABAI, M.D.,
Dean Madras Medical College&
Rajiv Gandhi Govt Gen. Hospital
Chennai-3.

CERTIFICATE

This is to certify that this dissertation in ***"FUNCTIONAL OUTCOME OF NONUNION LONG BONE FRACTURE TREATMENT BY LIMB RECONSTRUCTION SYSTEM-PROSPECTIVE AND RETROSPECTIVE STUDY"*** *is a bonafide work done by* ***Dr. S.KARTHIKEYAN*** *under my guidance during the period 2011–2014. This has been submitted in partial fulfilment of the award of M.S. Degree in Orthopedic Surgery (Branch–II) by The Tamilnadu Dr.M.G.R. Medical University, Chennai.*

PROF. M.R.RAJASEKAR

HOD &Professor,
Institute Of Orthopaedics & Truamatology
Madras Medical College &
Rajiv Gandhi Govt Gen. Hospital
Chennai- 600003.

DECLARATION

I, **Dr. S.KARTHIKEYAN ,** solemnly declare that the dissertation titled**"FUNCTIONAL OUTCOME OF NONUNION LONG BONE FRACTURE TREATMENT BY LIMB RECONSTRUCTION SYSTEM-PROSPECTIVE AND RETROSPECTIVE STUDY"** was done by me at the Rajiv Gandhi Government General Hospital, Chennai-3, during 2011-2014 under the guidance of my unit chief **Prof.M.R.RAJASEKAR , M.S (Ortho), D.Ortho.**

The dissertation is submitted in partial fulfilment of requirement for the award of M.S. Degree (Branch –II) in Orthopaedic Surgery to **The Tamil Nadu Dr.M.G.R.Medical University.**

Place:
Date:

Dr.S.KARTHIKEYAN.

ACKNOWLEDGEMENT

I express my thanks and gratitude to our respected **Dean Dr. KANAGASABAIM.D.,** Madras Medical College, Chennai – 3 for having given permission for conducting this study and utilize the clinical materials of this hospital.

I have great pleasure in thanking my respected teacher**, Director and HODProf .M.R.RAJASEKAR.M.S Ortho., D.Ortho**., for his valuable advice and guidance.

My sincere thanks and gratitude to my guide**Prof. N. DEEN MOHAMED ISMAIL. M.S. Ortho., D.Ortho.,** Professor of Orthopaedics, Institute of Orthopaedics and Traumatology, for his constant inspiration and guidance throughout the study.

My sincere thanks and gratitude to **Prof. V. SINGARAVADIVELU M.S.Ortho.,D.Ortho.,** Additional Professor, Institute of Orthopaedics and Traumatology, for his constant advice and guidance provided throughout this study.

My sincere thanks and gratitude to **Prof. A. PANDIASELVAM., M.S.Ortho., D.Ortho.,**Additional

Professor, Institute of Orthopaedics and Traumatology, for his valuable advice and guidance.

I am very much grateful to **Prof. R. SUBBIAH M.S.Ortho., D.Ortho.,** for his unrestricted help and advice throughout the study period.

My sincere thanks and gratitude to **Prof. NALLI R. UVARAJ M.S.Ortho.,D.Ortho.,** for his constant advice and guidance provided throughout this study.

My sincere thanks and gratitude to**Prof. ANBAZHAGAN M.S.Ortho., D.Ortho.,** for his constant advice, guidance and unrelenting support provided throughout this study.

My sincere thanks and gratitude to **Dr. Velmurugan M.S. Ortho.,**for his constant advice and guidance provided throughout this study.

I sincerely thank **Dr. Hemanth Kumar, Dr. Pazhani, Dr. Muthazhagan, Dr. ShanmugaSundaram, Dr. Manimaran, Dr. Karunakaran, Dr. Muthukumar, Dr. Kannan, Dr. Kingsly, Dr. Kailraj, Dr. Sameer, Dr. SenthilSailesh, Dr. Nalli R.Gopinath and Dr. Prabhakaran** Assistant Professors of this department for their valuable suggestions and help all during this study.

I thank all anaesthesiologists and staff members of the theatre for their endurance during this study.

I am very grateful to all my post graduate colleagues for helping in this study. Last but not least, my sincere thanks to all our patients, without whom this study would not have been possible.

Outcome analysis of non-union long Bones treated by Limb reconstruction system

CONTENTS **PAGE NO.**

Functional outcome of non-union long bone fracture treatment by limb reconstruction system both prospective and retrospective study.

Abstract:

Non-union of long bone fractures which was treated with Limb reconstruction system was followed up and the functional outcome was analysed in this study.Incidence of fracture long bone increased day by day due to increased RTA leading to increased incidence of nonunion. Controversy in treatment of nonunion regarding use of devices. Various devices are illizarov ,intramedullary nail, DCP, LCP, LRS etc. Basic requirements to all biomechanical stability & biological vitality of bones well provided by external fixator. Among these LRS external fixator simplest & effective devices with good union rates. LRS is easy to construct frame .LRS is less cumbersome to patients. LRS also have the facility to distract & compress the fracture & allow dynamization of fracture which are the essential principles in treatment of nonunion.Bone grafting, docking of fracture sites also can be done to achieve union. There is still controversy about union rates & complication associated with LRS in treatment of nonunion. So this study will be conducted to assess the union rate in fracture nonunion of longbone to assess complications associated with the devices. To evaluate the union rate with LRS in treatment of nonunion fracture long bones. To assess the duration of treatment with LRS in fracture nonunion of long bones.Fractures of long bone failed to unite by 6 months.All types of nonunion long bone. Radiological evidence of nonunion in fractures of longbones. Patient willing to give written informed consent. Patients who undergo LRS Fixator application for Nonunion long bones will be analysed for the following factors .Preoperatively the following factors are taken into consideration ,bone involved, Deformity, Condition of skin, Infection at nonunion site, Range of motion of adjacent joints, Shortening of the limb. Postoperatively the union is assessed by ,abnormal mobility at fracture site, Joint Movements, Loosening of LRS pins and Pin track infections. Radiologically the following factors are seen like ,Gap at fracture site ,Callus formation, Regenerate in cases of distraction osteogenesis. we selected 30 cases and analysed found that around 80% of union achieved by Limb reconstruction system.

Key words:

Limb reconstruction system,Dynamisation,nonunion ,docking.

INTRODUCTION

Nonunion is diagnosed, until clinical or radiographic evidence shows healing has ceased and that union is highly improbable. Nonunion is defined as “established when a minimum of 9 months has elapsed since injury and the fracture shows no visible progressive signs of healing for 3 months.” For every fracture this statement is not applicable, however A fracture of the shaft of a long bone should not be considered a nonunion at least for 6 months following an injurybecause union requires more time, especially after some local complications.

The exact causes of delayed union and nonunion are not clear. Some of the systemic and local factors are thought to contribute to their development. Following systemic factors are implicated in nonunion (i.e)patient’s metabolic and nutritional status, general health, and activity level, use of tobacco .Castillo et al. found that nicotine decreased blood flow at fracture sites and increases the development of bone infections. Hak et al. reported that tobacco use had a detrimental impact on the success of exchange reamed intramedullary nailing of femoral shaft nonunions and delayed unions. It has been shown that smokers have a decreased blood oxygen level, which leads to delayed wound healing. After abstaining from smoking these ptients will have better bone and

soft tissue healing. Additionally, nonsteroidal antiinflammatory drugs (NSAIDs) decreases fracture healing in multiple animal studies. Several human studies also revealed decreased fracture healing rates whereas many other studies refute the hypothesis that NSAIDs delay fracture healing. The literature is still conflicting regarding the influence of NSAIDs on fracture healing. During the course of treatment we advise the patients to abstain from NSAIDs and smoking. Boyd, Lipinski, and Wiley found in their review that local factors play a main role in management of nonunions of long bones. The common causes of non union were (1) open; (2) infected; (3) segmental fractures (4) severe comminution; (5) insecurely fixed fractures; (6) insufficient immobilisation; (7) improper open reduction of fractures; (8) undue distraction caused by external fixator or plates and screws; or (9) irradiated bone. Heppenstall et al., in a study of 185 nonunions of the tibia, found that 92.4% had an initial delay in weight bearing of more than 6 weeks. The severity of the trauma, open infected injuries, an unfractured fibula, and fracture in the lower third of the tibia also are other causes of non union in this series. Infected nonunion of long bones are not only a source of functional disability but also can lead to financial burden to the patients. Infected nonunion13, 32 has been defined as a state of failure of union with persistent infection for a period of 6 to 8 months at the fracture site. Infected nonunion can develop as a result of

open fracture, after a previous open reduction and internal fixation (ORIF), or as sequelae to chronic hematogenous osteomyelitis. The incidence also seems to be increasing especially in view of increasing high velocity trauma, which is more frequently treated with internal fixation. It is difficult to treat infected nonunion7, 13,44 because of the following reasons.

1. Cicatrisation of the soft tissue due to previous surgeries with an avascular environment around the fracture site.

2. The dead bone or sequestrum with a sinus tract near the fracture site,

3. Necrosis of bone near the nonunion site,due to thrombosis of blood vessels of Haversian canals.

4. Prolonged immobilization, multiple surgeries with fibrosis of the muscles leading on to a stiff joint/fracture disease.

5. Multiple antibiotics leads to resistance of microorganisms and poses a problem in controlling soft tissue loss with multiple sinuses[25, 15.]osteomyelitis,osteoporosis, complex deformities with limb length inequality, stiffness of the adjacent joints and multi drug resistant infection all complicate treatment and recovery.

The above factors play an unfavourable platform for fracture union. Outcome is poor even after repeated surgeries and prolonged treatment ultimately leading to amputation. Hence the treatment of non-union of long bones associated with infection is a challenge to the orthopaedic surgeon. The method known as the distraction osteogenesis[25] simultaneously corrects deformity, shortening, loss of bone function, osteoporosis and soft tissue atrophy. In the past there were several authors who put their mind in various modalities of treatment for infected nonunion by many methods where in all the factors of nonunion like deformity, shortening, infection and abnormal mobility were managed.

Stability and vitality of the bone, are the cornerstone of bone healing as they provide a favorable platform in which new bone can be formed. According to AO manual, External fixator is considered as the standard method of fixation in infected nonunion. Internal fixation is deferred in case of infected nonunion for the fear of persistence/ recurrence of infection. The limb reconstruction system is an unilateral external fixator system. Frequent complications like infection; bone gap, shortening of limbs, deformity and soft tissue problems with atrophic non-union makes LRS , an attractive option for skeletal stabilization.

AIM OF STUDY

The aim of the study is to analyze the outcome of treatment of infected Nonunion of long bones using limb reconstruction system both prospectively and retrospectively to reveal its real usefulness.

HISTORICAL REVIEW

Unilateral external fixator frame described by **Malgaigne**in 1853.

The frequency of malunion in femur, noted by **Keetley** in 1893,recommends rigid pin for external fixator.

Two half pins above and two half pins below the fracture in long bones described by **Parkhill** in1897.

Codevilla(1900) published the first result of a method of elongation of lower extremity.

Lambotte(1912) and Humphry (1917) were the first to advocate the use of threaded pins.

Pitkin and Blackfield (1931) were the first to advocate pins inserted through both cortices.

Anderson and O'Neil of Seattle (1933-1945) presented a series of papers concerning the use of half pins in leg lengthening procedures.

Anderson (1936) reported on his experience in femoral lengthening. **Phemister (1947) -** onlay bone grafting for treating nonunion.

Hoffman(1938 – 1954), his serial reports on external fixation brought an upsurge in their popularity.

Sir G.A.Ilizarov (1951- 1970) - Brought the concept of segmental transport by distraction osteogenesisthrough his research in soft tissue and bone regeneration & filled large segmental defects. His methodology marks the beginning of a new concepts, both scientifically & practically, which allowed the evaluation of previously unknown biological laws regarding bone transmission, osteo induction and tissue neogenesis. His technique was used even in the presence of infection.

Green - applied the principles of distraction osteogenesis to manage infected nonunion.

Unilateral external fixator is simple, but correction of mutiplanar deformities and large bone defects, couldnot be made. This lead to the invention of much stronger and versatile external fixator, the **ORTHOFIX**(Limb Reconstruction system) - at **Bussolengo, Verona. Italy**[6, 17.]

CAUSES OF NON-UNION

CAUSES:

FDA panel(1986) defined nonunion 7, 13,44 as “established when a minimum of nine months have elapsed since injury and the fracture show no visible progressive signs of healing for 3 months.”

Non-union can result from the following causes 7,13,44:

1. Excess mobility at fracture site -Due to less than adequate immobilization

2. Gap between fracture ends

(a) Interposition of soft tissues

(b) Malposition or overriding or displacement of fragments

(c) Loss of bone substance

(d) Distraction by hardware or traction

3. Loss of blood supply due to

(a) nutrient vesselsdamage

(b) Excessive stripping or periosteal injury

(c) Butterfly fragment, comminution of fractures

4. Infection results in

(a) Death of bone (sequestrum)

(b) Osteolysis (Gap)

(c) Implant loosening

5. Common pre disposing factors like

Age, Nutrition, Steroids, Radiation, Anticoagulants etc.,

CLASSIFICATION

Various classifications available for nonunion and infectednonunion in the literature and are as follows I. Judet, Muller, Weber and Cech 1,7,13,46 classified nonunion broadly intotwo types, they are

1. Hypervascular (Hypertrophic) nonunion - the ends of the fragments are capable of biological reaction.

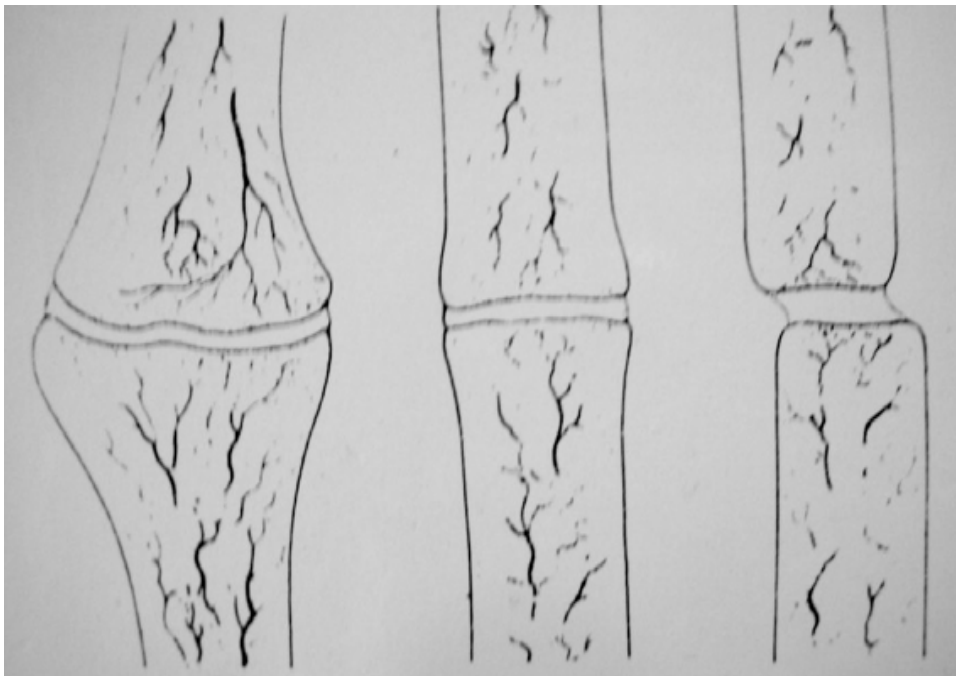
2. Avascular (Atrophic) nonunion - the ends of the fragments are inert and are incapable of biological reaction.

Hyper vascular/Viable/Hypertrophic nonunion further subdivided into

(1) Elephant Foot type

(2) Horse hoof type

(3) Oligotrophic type



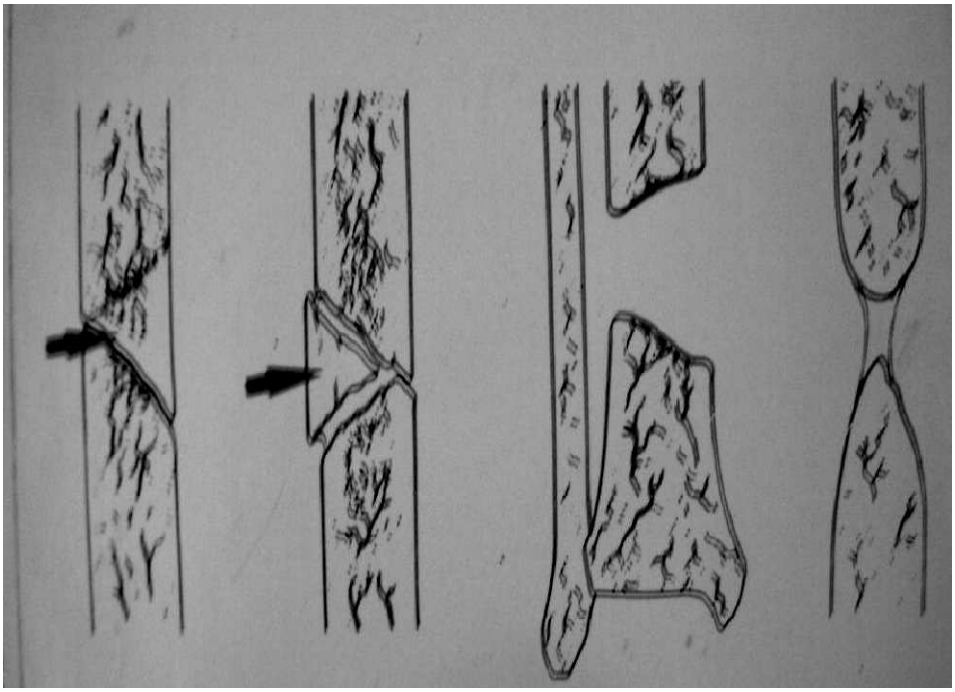
Avascular/Nonviable/Atrophic nonunion further subdivided into

(1)Torsion wedge

(2) Comminuted

(3) Defect

(4) Atrophic



The above classification based on viability of the fracture ends with or without infection is a radiological classification.

II. PALEY ET AL [1,7,13]divided non-union clinically and radiologically into two major types

Type A (Bone loss <1 cm)

A1- Nonunion with a mobile deformity

A2- Nonunion with a fixed deformity

A2-1 Stiff non union without deformity

A2-2 nonunion that is stiff with a fixed deformity

Type B (Bone loss>1 cm)

B1-Nonunion with bony defect

B2-Nonunion with loss of bone length

B3-Nonunion with bony defect and loss of bone length

This classification system is further modified by the presence or absence of infection.

III. MAURIZIO CATAGNI'S CLASSIFICATION [1, 46]

A1- Noninfected mobile nonunion

A2- Noninfected stiff hypertrophic nonunion without deformity

A3- Noninfected Hypertrophic nonunion with deformity

B1-Noninfective nonunion with bone defect of up to 5 cms

B2-Noninfective nonunion with bone defect exceeding 5 cms

B3-Noninfective nonunion exceeding 10 cms with local scarring

C1 -Infected nonunion with atrophy

C2 -Infected nonunion with hypertrophy without deformity

C3 -Infected nonunion with hypertrophy and deformity

C4 -Infected nonunion with bone gap of less than 5 cms

C5 -Infected nonunion with bone gap between 5 and 10 cms

C6 -Infected nonunion with bone gap exceeding 10 cms

IV. THE UNIVERSITY OF TEXAS CLASSIFICATION [46]

Based on the location of infection:

Type 1: Intramedullary

Type 2: Superficial

Type 3: Local

Type 4: Diffuse with segmental bone loss

Based on modification by immune competence of the host:

Type A: Healthy immune system

Type B: Local / Systemic compromise of immune system

Type C: Severe compromise of immune system

V. WIELAND CLASSIFICATION [46]

Chronic osteomyelitis according to this classification as a wound with open fractures, positive wound culture ,and pus discharge for more than 6 months.

Type I:open , bone exposed and with no features of bone infection but with soft tissue infection.

Type II: Presence of Circumferential, cortical and endosteal infection

Type III: Presence of Cortical and endosteal infection together with segmental bone loss.

VI. AO CLASSIFICATION[15, 44, 46]

1.Infected non-draining nonunion. (Active/Quiescent)

2.Infected draining nonunion.

To rationalize the treatment and for simplification we followed the AO

classification in our study.

ETIO-PATHOGENESIS OF INFECTED HARDWARE[7,13,44]

Various virulent factors are released by the bacteria,that react to the host's attempts at eradication . Glycocalyx (slime), a hydrated mucopolysacharide, which protects the bacterium and allows the bacterium to cling itself to metal hardware making it harder to eradicate deep infections . So it is always necessary to remove the hardware device if eradication of wound infection is to be obtained. This slime protects the bacteria in a sessile state increasing their resistance to destruction by a factor of 500. This layer protects the bacteria from the effects of antibiotics, antibodies and immune directed phagocytosis.

OSTEOMYELITIS AFTER PLATING:

Poor handling of tissues during exposure and fracture reduction, unnecessary stripping of periosteum at the fracture focus causes additional damage to the vascularity of bone fragments. Contamination at the fracture site leads to infection which spreads along the exposed bones and implants. Necrotic and infected bone fragments will eventually be demarcated and sequestrated with further loss of stability.

OSTEOMYELITIS AFTER NAILING:

Mostly occurs following open nailing, in open nailing with surgical exposure of the fracture site, additional periosteal stripping, and potential

contamination must also be taken into account. Blunt reamers and too large reamers can produce excessive heat and necrosis in turn can jeopardize the endosteal blood supply.

PINTRACT OSTEOMYELITIS:

Pin site complications include pin site inflammation, chronic infection, loosening, and metal fatigue failure. Most authors agree that infection rates from external fixation pins have steadily decreased as pin technology has improved but are still very far from zero. The most common pin site complications are now graded by the classification described by Dahl et al

Drilling with blunt drill bits at excessive speed and power causes heat necrosis of the cortical bone. Necrotic bone area may also result from forced insertion of Schanz screw or insertion of Steinmann pins into inadequate holes or without predrilling. Necrotic fragments in the form of ring sequestrum provide an excellent medium for bacteria, which migrate along the inserted implant into the wound. Bone resorption can be seen on X-ray, which is a sign of pin loosening. Occasionally chronic osteomyelitis reaching into the medullary canal may develop.

PRINCIPLES OF MANAGEMENT

1.ERADICATE INFECTION [7,13,44]

Electrical and electromagnetic stimulation, ultrasound, and bone graftingare the recent advances in the promotion of facture healing. The external fixator systems such as Ilizarov Circular external fixator, LRS have proved to be a versatile method for treatment of nonunions complicated by severe deformity, infection, and bone loss. Recent advances in internal fixation systems providesstable fixation to allow improved active and passive range of motion of adjacent joints as compared to the older systems ,enhancingadequate functional recoveryalong with bony union. There is still ongoing research in the use of bone grafts, bone graft substitutes, bone morphogenetic protein (BMP), and other new materials for boneregeneration.

The principles of treatment of infected nonunion begins with removal of all foreign material (eg.metal) and infected necrotic bone (sequestrum). Fracture ends should be debrided in such a way so that it increases the surface area of the opposing bone ends. The repairing process begins by restimulating a local inflammatory response. This can be supplemented by administration of appropriate antibiotics to eradicate infection.Commonly, the treatment of nonunionsbecomes complex as the

causesof the nonunion (infection, deformity, shortening, bony defect) increase in severity. The increasing severity of nonunionsas described in the classification systems of Judet and Judet; Müller, Weber, and Cech; and Paley et al. advocatemore cumbersome and complex surgical methods. Stable fixation alone contributes to the healing of Hypervascularnonunions, whereas decortication and bone grafting are required for atrophic (avascular) nonunions. As described by Paley et al., restoration of alignment, followed by compression contribute to healing of most type A nonunions. Type B nonunions may require additional corticotomy and either internal bone transport or overall lengthening to obtain the original bone length.The requirements common to all successful techniques are stability and vitality of the bone. These can be achievedby good reduction, adequate bone grafting, and good stabilization of the fragments. Three operations may be necessary to provide a normal skin.

1. Wound is saucerized and all foreign, infected, or devitalized materials are removed to provide a vascular bed. Gross deformity and displacement of the fragments are corrected through the wound. Internal Fixation has some advantages, but the use of foreign materials in an infected fracture site is ill advised. An intramedullary nail should not be used. If plates and screws are used, drainage almost always persists until

they are removed, but allows the fracture to be stabilized by fibrous tissue in satisfactory position.

An external fixator also can be used. This method is safer, but fixation is less stable thana plate fixation. Good antibiotic coverageparenterally and locally after surgery is given. Split thickness skin graft is applied 4 to 7 days after formation of granulation tissue over the raw area. 4-6 weeks after wound healing a full thickness graft is applied. A local rotation flap or vascularized free flap can be used to fill the soft-tissue defect left by the debridement. Bone grafting is not done until the soft-tissue graft has completely healed and has become stabilized. Bone grafting becomes unnecessary in some patients where the fracture has healed.

2. MAXIMIZE JOINT MOTION:

Second objective is to mobilize the joint to avoid contracture and arthrofibrosis. This can be achieved by the physiotherapy exercises, advised to the patient in the postoperative period.

3. CORRECT DEFORMITY AND LIMB LENGTH DISCREPANCY:

Minimal deformity can be corrected by taking appropriate wedge at the time of debridement. Shortening in upper limb can beacceptable, but

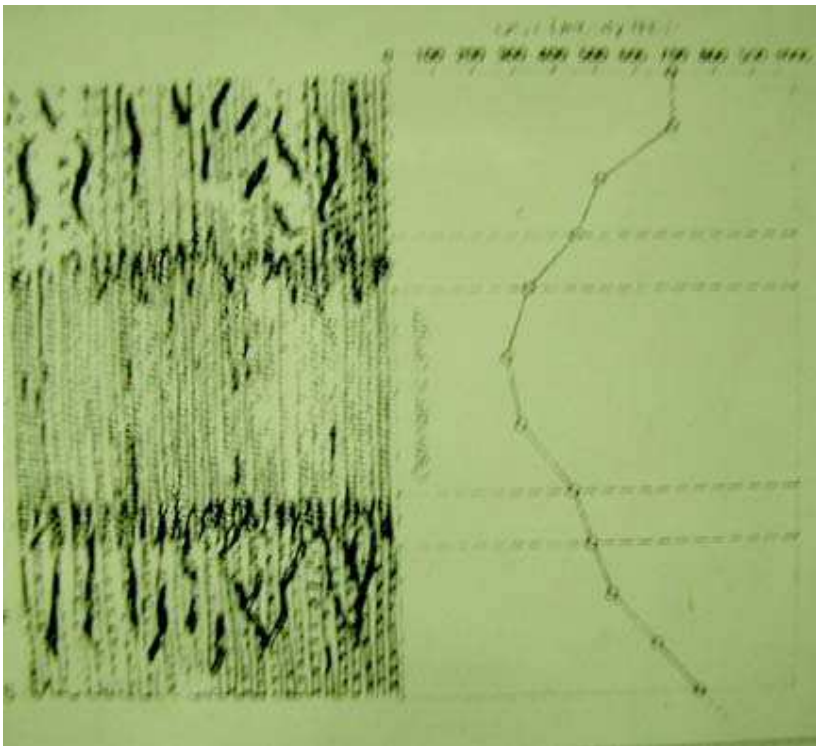
in lower limb shortening more than 2.5cms should be corrected by bone lengthening procedures.

4. ACHIEVE UNION:

The fourth objective is to achieve union in a reasonable amount of time both at the nonunion site and the corticotomy site. The distraction compression osteosynthesis increases the blood supply of the whole limb as well as the fracture site, which is advantageous for union. Compression produces local necrosis in the fibro cartilaginous tissue and inflammatory reaction stimulates the bone healing process.

D.DISTRACTION OSTEOGENESIS.

SCHEMATIC DIAGRAM OF HISTOLOGY



DIFFERENT ZONES DEMONSTRATED HISTOLOGICALLY AND BY QCT STUDY.

FIZ- Fibrous Inter Zone

PMF-Primary Mineralization Front

MCF-Micro column Formation

Advantages:

(i) Minimally invasive, Pins are percutaneous and normally requires only minimal soft tissue handling

(ii) Osseous tissue generation can be promoted

(iii) Versatile

(iv) Helpful in acute or chronic infection

(v) intra-articular or periarticularstabilization of bone fragments

(vi) deformity correction &promotion of bone healing

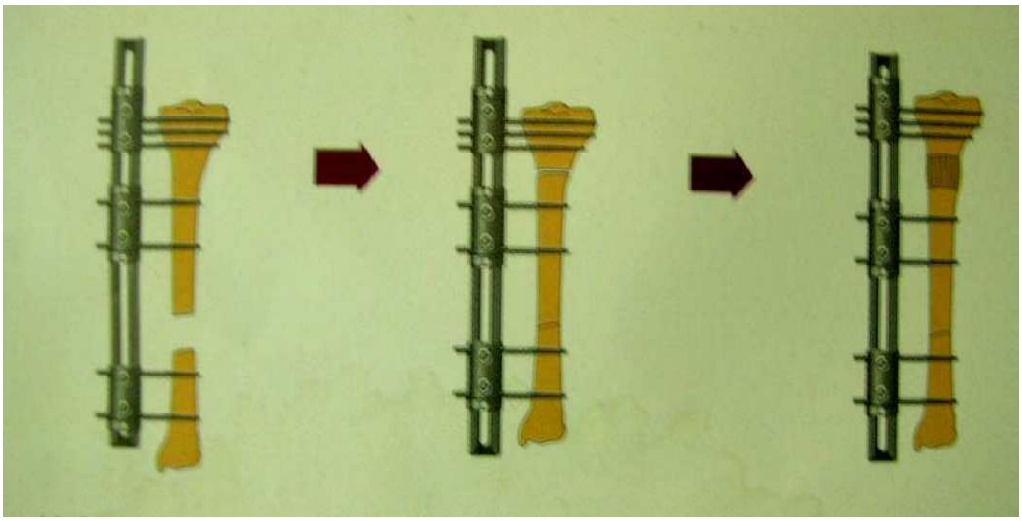
(vii) Allows weight bearing immediately&early return of joint function

(viii) Enhancement or changes can be done by frame adjustment

(ix) Shear &rotational forces are resisted while the tensioned wires allow the “trampoline effect” while weight-bearing.

The Limb reconstruction technique reduces and stabilizesall types of deformity, including complex deformities, and corrects limb length discrepancy. Limb reconstruction technique,can be used in the following modes namely distraction-lengthening, and simultaneous correcting various deformities in the same bone. Monofocal lengthening and bifocal lengthening exits ,inmonofocal lengthening single distraction site exit whereas in bifocal lengthening two sites undergoing distraction.

Distraction-Lengthening - At the corticotomy site the bone lengthening occurs by distraction osteogenesis . Distraction leads to tension-stress effect ,that causes increased blood supply and proliferation of cells in many tissues, including regeneration of bone mainly through intramembranous ossification.Profound biological stimulation occurs at corticotomysite due to distraction osteogenesis similar to bone grafting.



A variety of mechanical and biologic factors affect distraction osteogenesis.

(1) low-energy technique must be used for performing the corticotomy or osteotomyto minimize necrosis of bone.

(2) Corticotomy should be done at the metaphyseal or metaphyseal-diaphyseal regions rather than the diaphysis

(3) A stable external fixator system

(4) a latency period of 7 to 14 days after corticotomy is ideal before beginning bone transport

(5) adjust the rate and rhythm of distraction according to the progress of regenerate formation as seen in plain radiographs as some patients may have a slow regenerate formation.

(6) fixator removal should be after complete consolidation of the regenerate which is approximately 2 to 3 times the time of bone transport.

BIOLOGY OF DISTRACTION OSTEOGENESIS:

During distraction, a fibro vascular interface is arranged parallel to the direction of the distraction while new bone columns add length to the gap. When biology and mechanical conditions during distraction are ideal, bone is formed by intra membranous ossification.

HISTOLOGY:

Biopsies taken from mid-sagittal plane along the tibial crest of the experimental animal. Bones sectioned by a Bronwill saw. Using electron microscopy Back-scattered scanning method confirms the micro radiographic measurements with three-dimensional orientation and localized calcium deposits by microprobe analysis. Early specimens

came from distraction started at day 7 , at a rate of 1 mm per day and a rhythm of 0.25 mm four times a day. A fibro vascular network bridged the distraction gap,at this point of time., There was no evidence of mineralization. Each micro-cone of bone surrounded by large vascular channels on all surfaces. These vessels contained a thin lining of endothelial cells, with internal diameters up to 400 microns.

VASCULARSTUDIES:

India ink injection on day 35 demonstrated both afferent and efferent vessels across the osteogenic area. In coronal section very few vessels crossed the fibrous interzone. The vessels were clearly oriented parallel to the distraction force and the new columns of bone. Technetium scintigraphy provided in vivo measurements of blood flow and bone formation related to normal zone in the experimental models.

MINERAL DENSITY STUDIES:

The weekly changes in bone alignment and gap formation during distraction was assessed by Plain radiograph and it was adequate for documentation.. The bridging of the osteogenic area and remodeling of the bony macrostructures into cortex and medullary canal was assessed in quantitative computer tomography (Q.C.T),which clearly demonstrated

the volume of mineralization within osteogenic area preceded visualization by plain radiography.

MECHANICAL FACTORS:

The rate of distraction should remain within a range of 1 mm per day. Slower rates allow premature fracture healing to proceed and bridging of the gaps. Faster rates of distraction seems to out strip advancing blood supply and inhibiting mineralization.

Rhythm is defined by the number of actual distractions to be done each day. Adequate osteogenesis occurred at the rhythm of 0.25 mmm every 6 hours. At one millimeter once daily osteogenesis is significantly inhibited. Time period between the operation and the initiation of distractionis the latent period. The average recommended latency period is from 4 to 7 days. Osteogenesis may proceed in an angular fashion, but the angles may be unintended.

Jorge.E.Alonso and Pietro Regazzoni - divided the treatment period into three phases.

1.TRANSPORT PHASE:

During this phase,the bone is transported from corticotomy site ,advancement of the segmental defect until it reaches the other end of the

bone, and Docking of the fragment occurs. Ilizarov has demonstrated that intra membranousossification occurs during distraction.

2.MATURATION PHASE:

During this maturation phase an increase in the mineral content of the regenerate area can be seen. The quality of regenerate can probably be improved by, soft tissue coverage of the open areas with rotational or free vascular flaps.

3.CONSOLIDATION PHASE:

This is a compression phase, during which the cortical bone content increases to about 80%. Once the segment reached the distal fragment, the interphase can be improved by methods like plating and cancellous auto grafting to reduce duration of consolidation phase.

E.BIOMECHANICS OF LIMB RECONSTRUCTION SYSTEM:

In Limb reconstruction system bone grip is achieved optimally using half pins. The Limb reconstruction system screw is made of AISI 316L ESR stainless steel [17]. A practically impurity-free alloy is obtained by electros lag refusion. The steel is also subjected to a cold surface hardening deformation process that increases its yield strength from 50

da N-mm –2 to80 da N.mm-2.This material shows excellent resistance to yield loads.

Depending on the type of bone tissue in which the screw has to be inserted, the pitch is determined. For cortical bone, It is 1.75mm and for cancellous bone it is 3mm

While inserting the screw, to reduce thermal damage &to improve the mechanical properties of the construct, the correct relationship between drill and screw diameters, and the profile of the thread of the screw will be of help For cortical bone screws, the most suitable drill diameter is 4.8mm and for cancellous screws 3.2mm. Pins tapered 6 to 5mm is suitable for femur and tibia, pins tapered 4.5 to 3.5mm is suitable for humerus.

Wikenheiseret al[17] compared the thermal effects of screws & came to a conclusion that the tapered LRS screws generated the lowest temperature, always below the limit of 50°C. (considered the highest permitted temperature to avoid thermal necrosis)

TAPERED BONE SCREWS

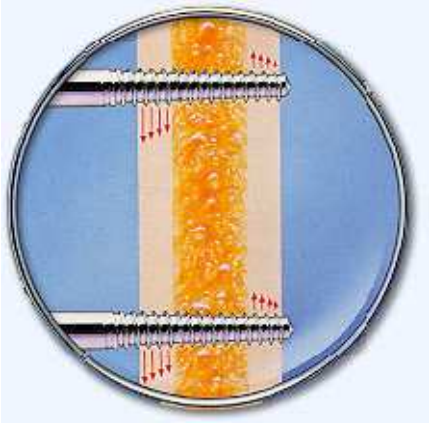
Tapered Bone Screws are "Designed for Increased Holding Power".Betterpurchace of screws in the bone.Reverse turn is not allowed

in the screws,because once reverse turn allowed makes the screw loosened because of tapering ends.

Successful external fixator requires a good pin-bone interface;

Pin loosening occurs due to the following reasons,

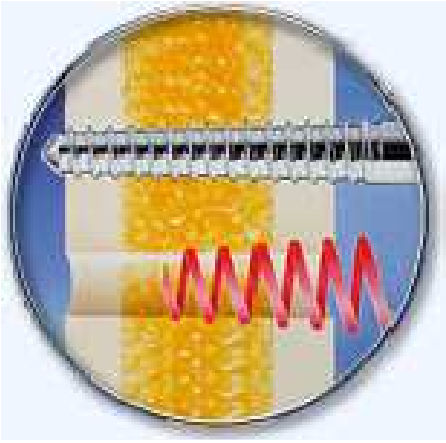
1. Bending of LRS screws
2. Loading which is unequal
3. Pre-tensioning of LRS pins
4. Infection of pin site



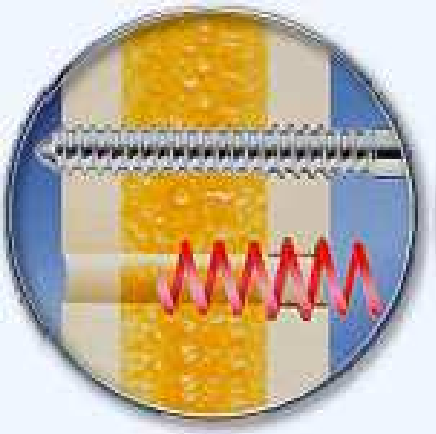
All these causes loosening around the pin hole which ultimately results in pin loosening. The features of the Limb reconstruction system tapered screw helps in getting a better purchase in the bone and for stable fixation. Higher resistance offered by Tapered screw to bending where it is most needed i.e., at the near cortex.

Unilateral fixator exerts maximum load on the near cortex (ie.,60-70%).

The greater screw diameter ensures a higher resistance to bending force at near cortex. On insertion of tapered screw, each screw thread creates a new and largertrack in the bone.



Pre-drilling helps in reducing the amount of force required to insert a screw thereby ensuring distribution of loads evenly.The tapered screw design, peculiar geometry produces efficient radial Preload andhelps to provide excellent bone purchase. It has been shown that dynamisation in the LRS reduces the stress on the screws and improved screw fixation stability. Even partial backup of screw results in loss of bone grip is the main disadvantage of this system.



The ''Non-Orthofix' uniform diameter screw –ie.,schanz pin screws

During insertion, grooves cut by the previous threads will be occupied by each successive thread of the screw. This causes sustained & repeated erosion of the grooves in the bone. While encountering the far cortex, difficult bone penetration. The surgeon has to apply extra force to insert the screw and during the procedure, when done rapidly, the screw may advance into the bone like a wedge & the cortex may be ruptured. Purchase may also be less than ideal, as the flute interrupts continuity of the thread. While encountering the near cortex, the screw may damage the grooves , so that the screw tract may get enlarged,which may leads to uneven weight distribution and failure of pins ie., loosening.

The advantage of Limb reconstruction system tapered screws; They can be removed without any hassles in the outpatient department.

The tapered pins are easy to remove in the clinic because all of the threads become loose after the initial turn.

Limb reconstruction system screws

The various types of screws used in LRSare cortical screws, cancellous screws and "cutting edge" screws for lengthening and bone transport procedures. Standardized screw introduction technique designed to ensure with negligible trauma to surrounding soft tissues.

Hydroxyapatite coated pins can be used in osteoporotic bone, which has the ability to improve the interface between bone and implant.

Postoperative care of the pins is essential for the trouble-free pin sites , which is necessary for the successful external fixation procedure so that the infections can be reduced.

During pin placement the soft tissue tension should be avoided to minimize pintract infection .The fundamental principle[5,31] for pin placement especially when distraction osteogenesis is attempted is that the pins should be parallel to the adjacent joint in all planes. The nuts on the Limbreconstructionsystem apparatus are tightened with a torque wrench (Allen key) that is provided.

REUSAGE[49]:

The apparatus includes various clamps, made of hard anodized Aluminium alloy.Once the limb reconstruction system apparatus has been completely used, the entire apparatus is dissembled; discard the tapered pins because they should not be reused. Immerse the dissembled parts of LRS apparatus in 36 volume of Hydrogen peroxide for more than 12 hrs, any residue remaining are brushed in running water, then soaped in distilled water, as this will remove traces of hard water.

After the above treatment the apparatus is dried and sent for re-sterilization for the next usage.

THE ORTHOFIX AND THE LIMB RECONSTRUCTION SYSTEM (LRS):

Experimental data as well as clinical studies have shown us that same effect can be obtained with many fixators. Whenever possible the assembly should technically be easy and comfortable to the patient. Unilateral fixators meet these prerequisites. The advantage of the monolateral dynamic axial system is that it is a modular concept, which allows different constructs from simple to complex assembly.

Preoperative planning of screw placement, corticotomy site, and fixator orientation is necessary. The fixator is applied following the principles of application of external fixator.

The LRS (Limb Reconstruction System) consists of rails[40] of 240mm, 300mm, 400mm,to which multiple sliding screw clamps are attached, one clamp per segment of bone. Straight longitudinal clamps with longitudinal screw clusters are used unless small metaphyseal segments require fixation, in which case a T-clampfor transverse screw orientation is used. The rail must be parallel to the bone that is stabilized with accurate bone alignment. To achieve this care must be taken in applying the most distal and proximal screws because once these are applied, subsequent adjustments in limb alignment are not possible. If these two screws are both applied perpendicular to the axis of the bone, the rail ends up parallel with the bone, and accurate limb alignment, bone transport, and eventual docking are ensured 40. The location of the most proximal and the distal screws depends on the location of the defect and the planned corticotomy site. For proximal tibialcorticotomies, the first screw should be in the flare of the proximal tibial metaphysis. When the second screw is inserted rotational alignment must be correct. At the time of application of the screw, the middle clamp's position should be verified. Bicortical purchase of all screws must be verified. After all

screws are placed, the template clamps are replaced by the definitive fixator clamps, and the

LRS is tightened into place.

INDICATIONS:

The device can be used for the following indications

1. Fixation of fractures

2. Correction of diaphyseal/metaphyseal deformities either with or without shortening.

3. Bony and soft tissue deformity correction

4. Limb lengthening

5. Malunion and nonunion treatment.

6. Transporting bone

CONTRAINDICATIONS:

1. Severe Angulations and deformities, which can be better treated by Ilizarov.

2. Severe osteoporosis.

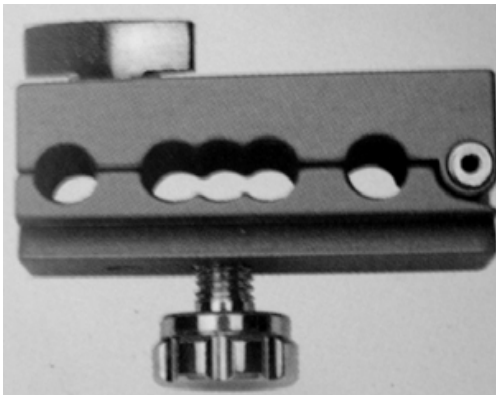
3. Non compliant patients

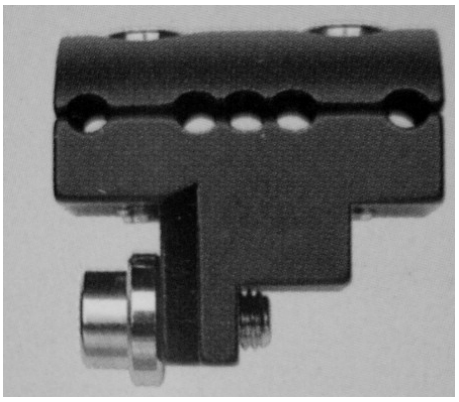
Preoperative planning isnecessary inorder to reduce the operative time and to ensure full armamentarium of components before surgery. Appropriate size of rail, clamps, tapered half pins and drill bits are selected. Tapered half pins should be in strict anatomical consideration avoiding damage to nerves and vessels. The tapered half pins should be gently negotiated through the soft tissue, and should not be drilled. All components are tightened or fastened with appropriate instruments.

THE PARTS OF THE LIMB RECONSTRUCTION SYSTEM:

STRAIGHT OUTER CLAMP STRAIGHT CENTRAL CLAMP

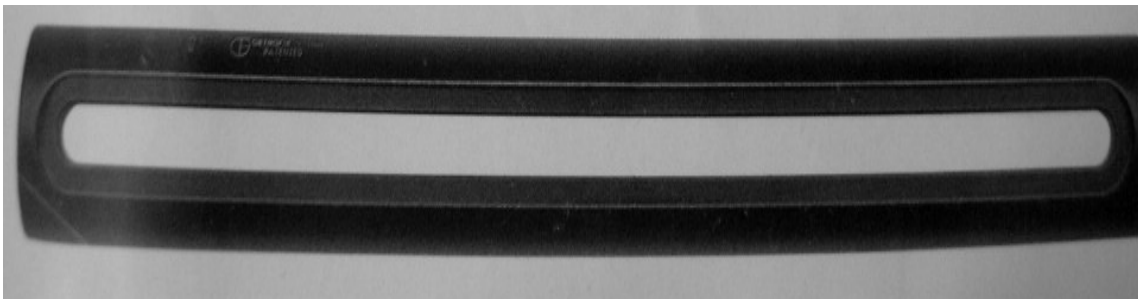
TEMPLATE FOR STRAIGHT CLAMP T-CLAMP





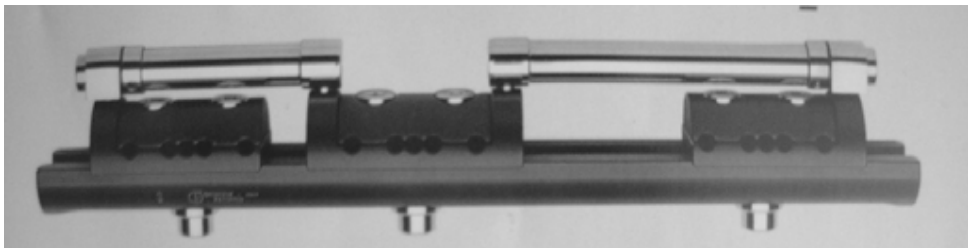
DISTRACTION COMPRESSION UNIT

RAIL



TAPERED BONE SCREW

FIXATOR ASSEMBLED



The same principles have been applied in the Indian version of orthofix system namely the Dynamic External fixation system and the Rail Fixation System.

MATERIALS AND METHODS

MATERIALS:

This is a prospective and retrospective study conducted at Rajiv Gandhi Govt. General hospital ,Chennai which consists of 30 cases in the age range from 20 yrs to 65 yrs (with a mean age of 35.6 yrs.) who were treated at our institution from July 2011 to Sep 2013.Patients who were lost to follow up were not included in this study. Our institution approved our treatment protocols and all patients gave written informed consent.

There were 26 males and 4 females in our study with male to female ratio of 6.5:1

These infected nonunion were classified by the AO Classification [15, 44]. In our study, according to this classification we had

1. Infected quiescent non- draining nonunion – 6 cases
2. Infected active non-draining nonunion – 6 cases
3. Infected draining nonunion –18 cases.

Patients with wounds that had no discharge for 3 months were labeled as non-draining (Quiescent). Infection was evident by local

symptoms and signs like increase warmth, redness, sinus, fever, etc,.13 patients had infected nonunion of femur, 17 patients had infected nonunion of tibia. Of the 13 cases of femur, 5 had infected nonunion after ORIF with nail/pate for closed fractures, 4 had infected nonunion which occurred after open fractures and subsequent native treatment, and 4 had infected nonunion following treatment of open fracture with AO external

fixator system.Among the 17 cases of tibia, 4 patients had infected nonunion after ORIF for closed fracture, 9 infected nonunion occurred after open fracture ,6 patients had infected draining nonunion. Our follow up period was with a maximum of 18 months to a minimum of 5 months (mean 8.3 months). The bone involved and the type of nonunion, along with the number of cases and age distribution are given in table 1,2,3,4.In Toto, of the 30 cases, infected nonunion resulted from previous surgeries in 9 cases. In 6 cases infected nonunion resulted

from improper treatment of the open fracture by native bone setters and in 2 other cases infected nonunion resulted after cast immobilization for Grade 1 open fracture **(Gustillo Anderson classification)** and 13 cases of Grade III b open fractures treated with external fixator initially.

Diagnosis was established by history physical examination and investigations like erythrocyte sedimentation, total and differential white blood cell count, pus culture sensitivity and standard AP, LATERAL X-

rays. History is taken from the patient including the date of injury, detail of original accident and subsequent treatment. Special attention was focused on limb length measurements, range of motion ofthe joints, neuromuscular status and distal vascularity. 9 cases of infected non-union had knee stiffness, 9 cases had ankle stiffness.

TABLE-1:

DISTRIBUTION OF NON UNION	**NO.OF.CASES**
FEMUR	13
TIBIA	17

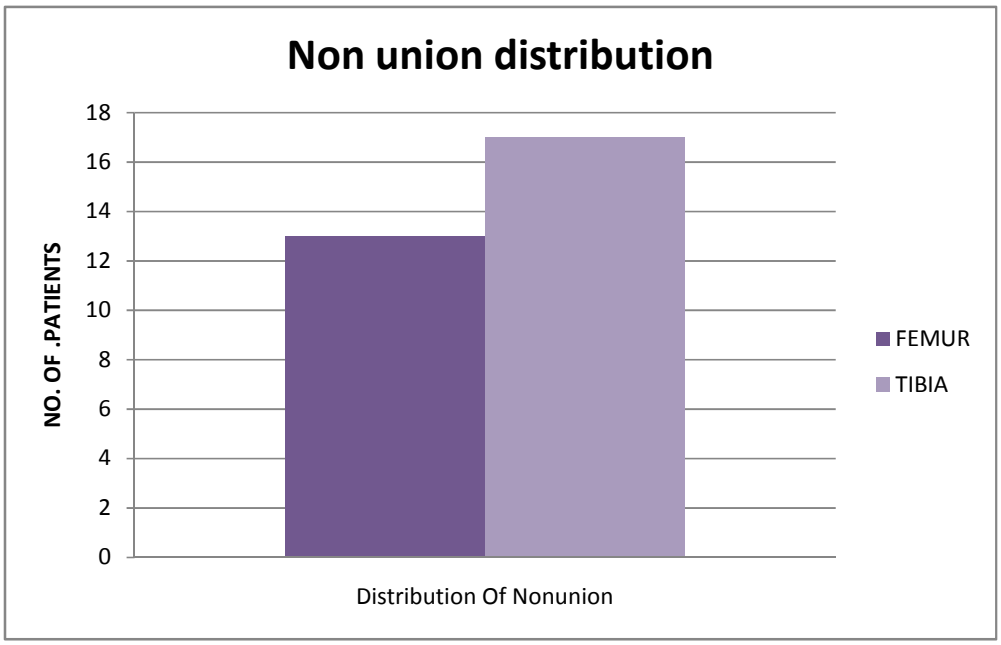
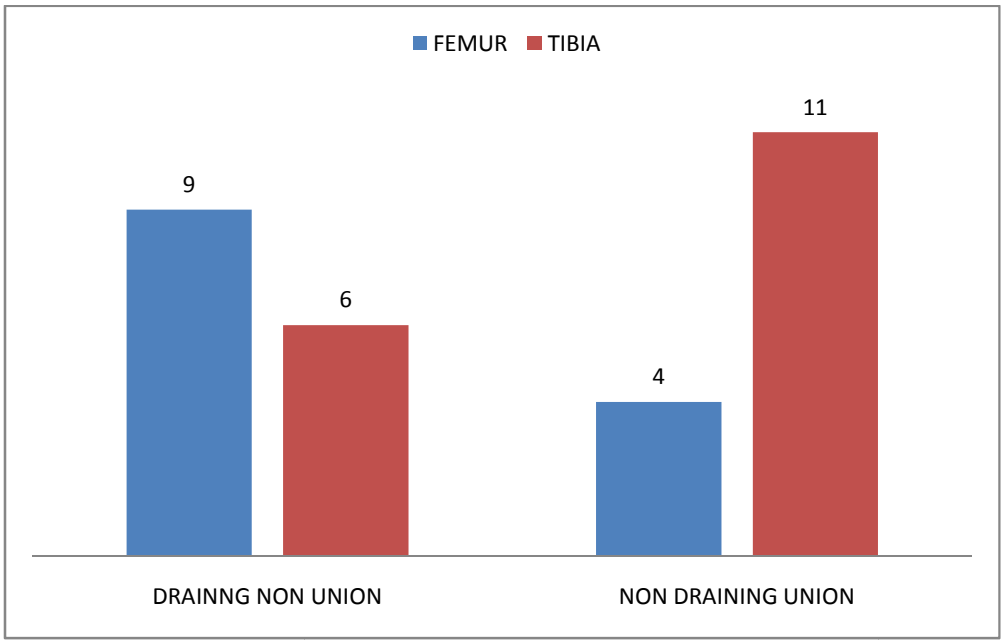


TABLE 2

BONE	DRAINING NONUNION	NON DRAININGNONUNION
FEMUR	9	4
TIBIA	6	11


FEMUR
TIBIA
9
6
4
11
DRAINNG NON UNION
NON DRAINING UNION

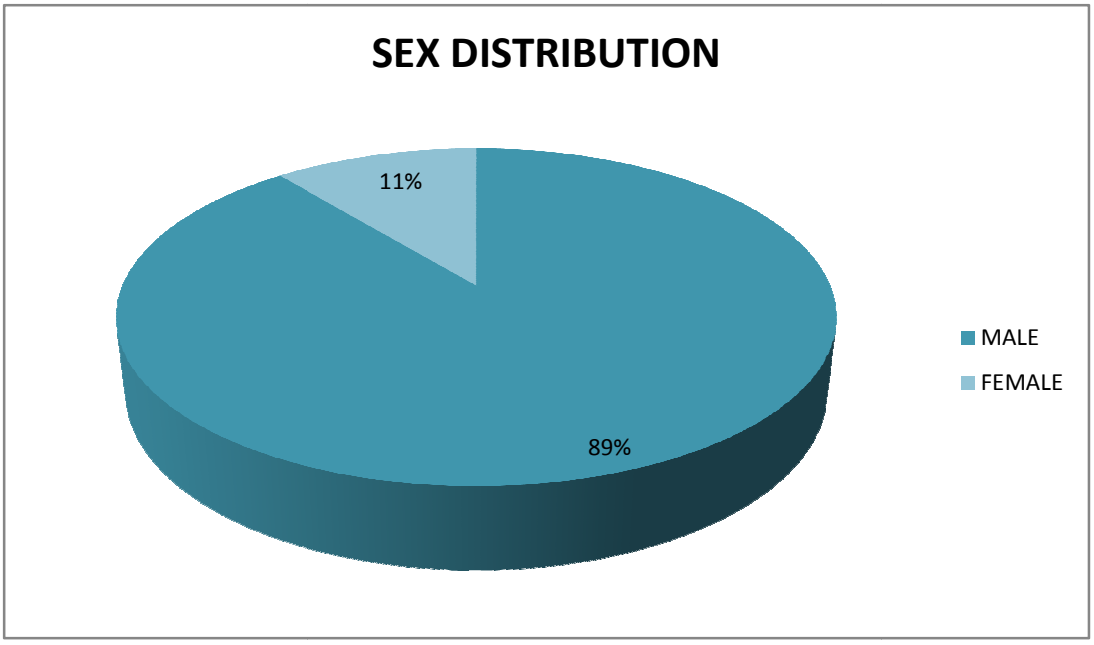

SEX DISTRIBUTION
11%
89%
MALE
FEMALE

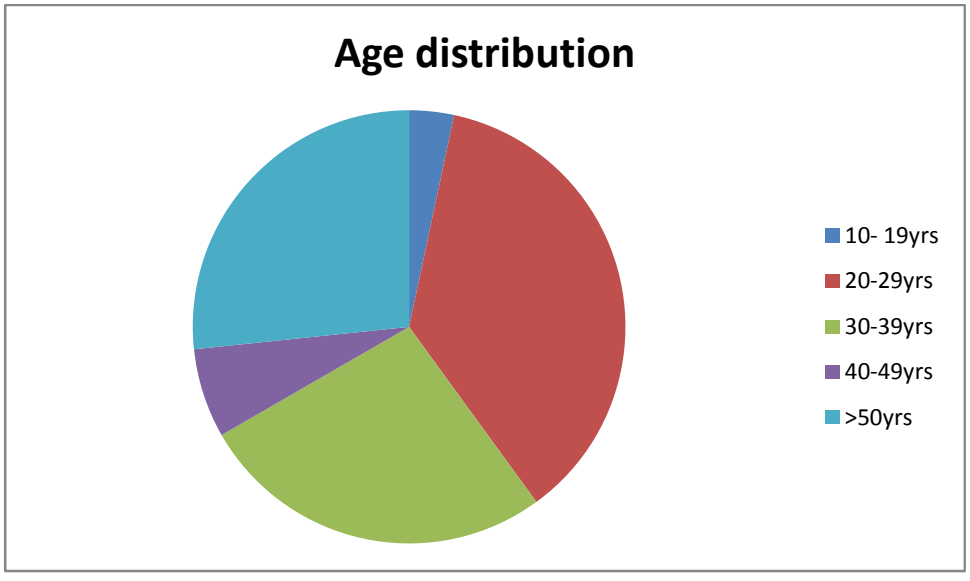
TABLE 3

INFECTED NONUNION	TOTAL	POP	EXTERNAL FIXATION	PLATING	NAILING
FEMUR	13	-	4	3	6
TIBIA	17	4	6	3	4

TABLE 4

AGE DISTRIBUTION

10-19 YEARS	1
20-29 YEARS	11
30-39 YEARS	8
40-49 YEARS	2
ABOVE 50 YEARS	8



METHODS:

The cost of the original Limb reconstruction system is high. The price is beyond the reach of our patients. Various Indian versions of Limb reconstruction system have been introduced in the recent past, which is much cheaper than the original and is available at an affordable price for the patients. We did not come across gross deformity as most of the cases in our study have had previous surgeries and the problem was mainly infected nonunion with minimal deformity. The most common organism isolated from draining nonunion was staphylococcus, other than that pseudomonas, proteus, klebsiella were also isolated in different cases. Based on the culture report specific antibiotics were chosen and given to patients. Antibiotics have always been considered as complementary to surgery.

SURGICAL PROCEDURE:

ANAESTHESIA:

Spinal anesthesia is preferred for lower limb surgeries.The appropriate parenteral antibiotics, which the patient has been taking preoperatively for infection, are administered before the start of the surgery and continued post operatively.

Through previous scar if surgery has been done already, thorough wound debridement and excision of the infected soft tissue and necrotic bone till fresh bleeding appeared(Paprika sign.)39, was done. The sinus tract, infected soft tissue, and unhealthy granulation tissues was excised and sent for histopathological and culture study. The medullary canal was opened on either side by gentle reaming. Monolateral external fixator was applied following this. The most distal and the proximal screws were applied first and tightened after making sure that the limb is in proper alignment and rotation, remaining screws were passed subsequently. In all the cases acute docking was done at the nonunion site and compression given. The operative field was thoroughly irrigated and wound closed by stay

sutures. In some of the cases drain was kept, which was removed after 48 hrs.

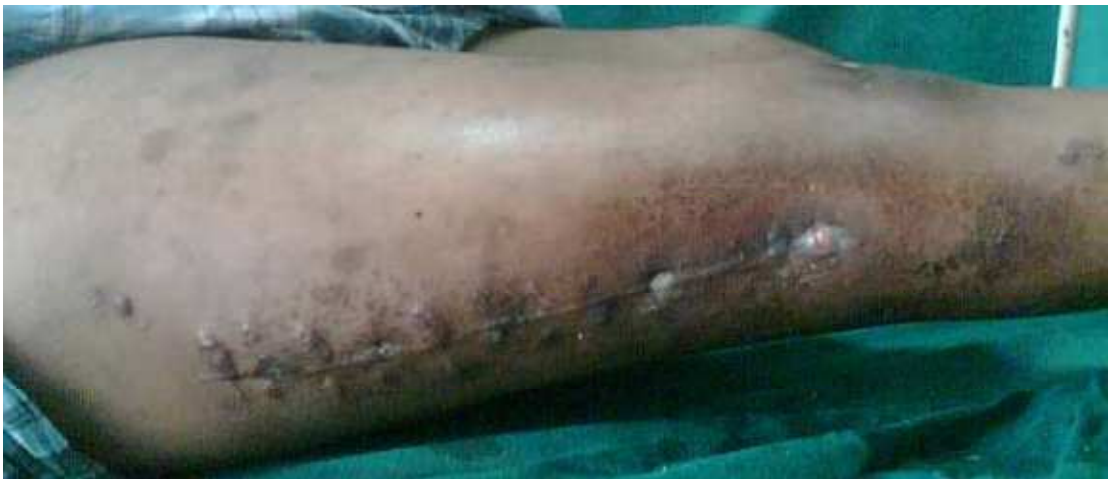
In four cases there was wound dehiscence, which healed after skin grafting after the formation of healthy granulation tissue. In 23 of our cases the shortening was ranges from 1 to 4 cms (mean 1.44 cms.) acute docking was done at the debrided site and osteotomy was performed distal to the tibial tuberosity at the proximal metaphyseal area for tibia and osteotomy for femur at the proximal third by means of separate set of instruments so as to prevent introducing infection at the osteotomy

site. An open approach is made to perform corticotomy by means of multiple drill holes which is made complete by osteotome. Attention should be paid to preserving periosteum because it has a major role in osteogenesis. Segmental resection of fibula was done in leg to allow acute docking. Distraction was started on the 7 thpost operative day1, 32. the fixator was always applied to the lateral aspectfor femur, and medial aspect for the tibia. In the hospital the distraction was done by the surgeon and afterdischarge from the hospital this was done by the patient or his relatives. To know the exact direction of rotating the key the patients asked to mark with marker over the compression and distraction set. In all of the cases after debridement acute docking was done at the nonunion sites, as the maximum amount of bone loss we encountered was 5 cms. Distraction was carried on for a period of minimum 34 days to a maximum of 58 days (mean 46.6 days). The length of bone gained was from 3 to 5 cms. (Mean 4.2 cms.). In some of the cases supplementary procedures like skin grafting, flap cover, revision of pins and bone grafting were carried out.

In spite of through debridement and antibiotics, infection did not get controlled in 8 cases.

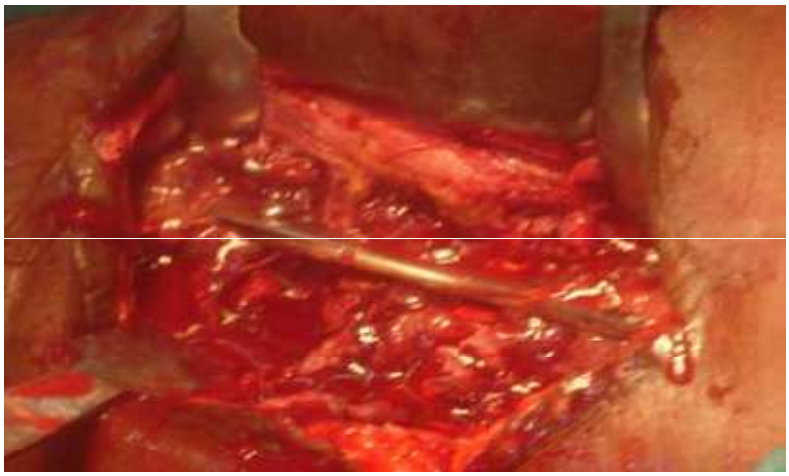
ORTHOFIX FIXATOR (INDIAN VERSION)

DISCHARGING SINUSES

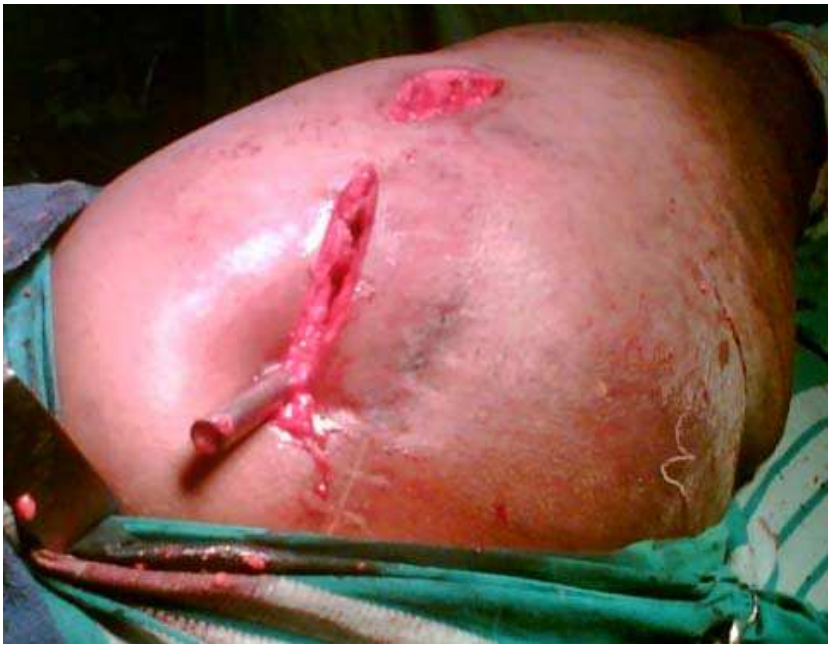


INTRA OPERATIVE PHOTOS

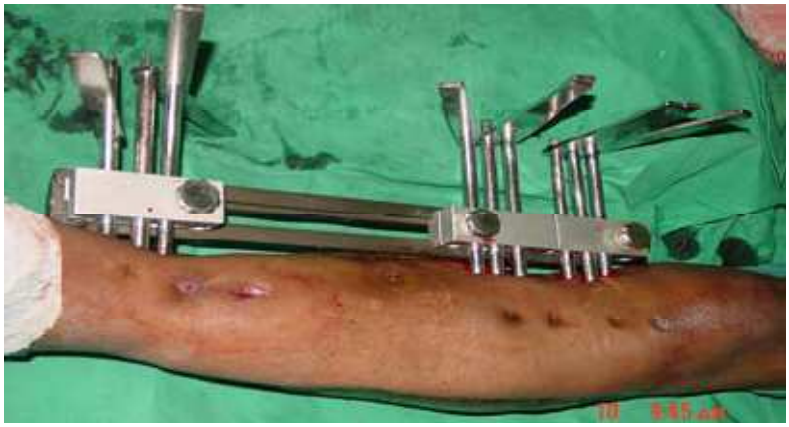
INFECTED PLATE-REMOVED



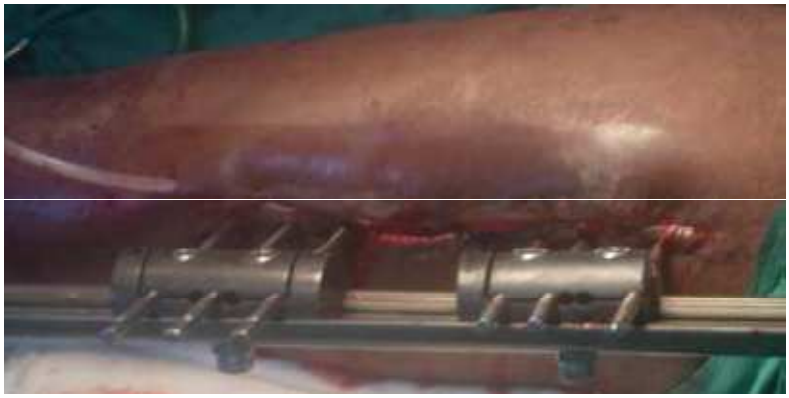
INFECTED NAIL REMOVED



TEMPLATE USED BEFORE APPLYING DEFINITIVE CLAMPS



FIXATOR IN PLACE



POST-OPERATIVE PROTOCOL

Post operatively, the limb is kept elevated to reduce the post-operative edema. The ankle is splinted in neutral position. Drain is removed after 48 hrs. Parenteral antibiotics were continued for 2 weeks post operatively or till the subsidence of infection and then oral antibiotics were given for an additional 2 weeks. Joint motion exercises and non-weight bearing followed for 4 weeks and then partial weight bearing was advised. Distraction was carried at the rate of 0.25 mm fourtimes a day, which was started from the 7 th postoperative day1, 32. Radiograph was taken every week during the initial period of distraction and at monthly interval thereafter. On discharge, all patients were taught about pin site care, hygiene and the rhythm of distraction where lengthening procedure was carried out. The patients were followed in the out patient department, where clinical and radiological assessment was made. The rate of regenerate formation determined the rate of distraction. In all cases compression at the nonunion site was maintained until union was achieved. Encouraging weight bearing and alternate compression – distraction altered the poor consolidation of the regenerate (Accordion technique). The distraction was stopped when sufficient length of regenerate was achieved. The fixator was left in position for a further period for consolidation of regenerate. In six cases, in spite of successful

docking and control of infection, there were no signs of radiological union; bone graft was applied at the compression site. The criteria for radiological union are the presence of bony consolidation in three out of four cortices in AP and Lateral x-rays. When this is achieved, the patient is examined clinically and the fixator is removed. After removal of the fixator patient is advised to use functional cast brace and crutches for lower limb for a period of 6 weeks during which the patient is gradually mobilized to full weight bearing.

RESULTS

ANALYSIS:

In the last 32 months we had the opportunity to treat 30 cases of infected non-union with Limb reconstruction system. Of the 30 patients 19(73.3%) patients developed infected nonunion following open fracture and 11 patients (26.6%) developed infected nonunion following previous implant surgeries for closed fractures. Our follow up of cases varied from 5 to 18 months (mean 8.3 months).

Union time ranged from 4 to 8 months (mean 4.9 months). Sinus tract got cleared in all cases except 6 where the sinus tracts were multiple and there was no progression towards union in those cases. There was no difficulty in this series as far as transportation of bone. There was considerable delay in the consolidation phase in all cases. Out of 30 cases 12 cases had pin tract infection (40%). For wound dehiscence in the post operative period, split skin graft cover was given in 6 cases. During transportation phase in bone lengthening procedure there was pin tract infection and loosening in two cases for which pin revision was done. In all cases there were no infection at the corticotomy site. After a period of waiting for consolidation to occur, the final result of the healing of the osteotomy was adequate in all 9 cases. The cases with limb length

discrepancy up to 2.5 cms in lower limb managed with modified footwear with heel and sole raise. The results were divided into bony results and functional results, according to the classification of the ASAMI 1,15 (Association for the study and application of the method of Ilizarov). ASAMI'S criteria were used to analyze the results in our study, as there were no specific criteria available in the literature for assessing the results after treatment with Limb reconstruction system fixator.

BONE RESULTS:

The Criteria for determining bone results (ASAMI) are as follows:

(1) Union

(2) Infection

(3) Deformity

(4) Leg length discrepancy.

The fracture is said to be united byroentgenographically, when there was no mobility at the site of nonunion after loosening all nuts in the apparatus and the patient was able to walk without pain and had a feeling of solidity of the limb.

ASAMI CRITERIA:

According to the protocol of the ASAMI.

Bone union results:

E-Excellent -Union + No Infection+ Deformity<7 degrees+ Shortening<2.5cms.

G-Good - Union + any TWO of the above factors.

F –Fair – Union with any ONE of the above factors.

P-Poor -No union or Refracture or none of the above factors.

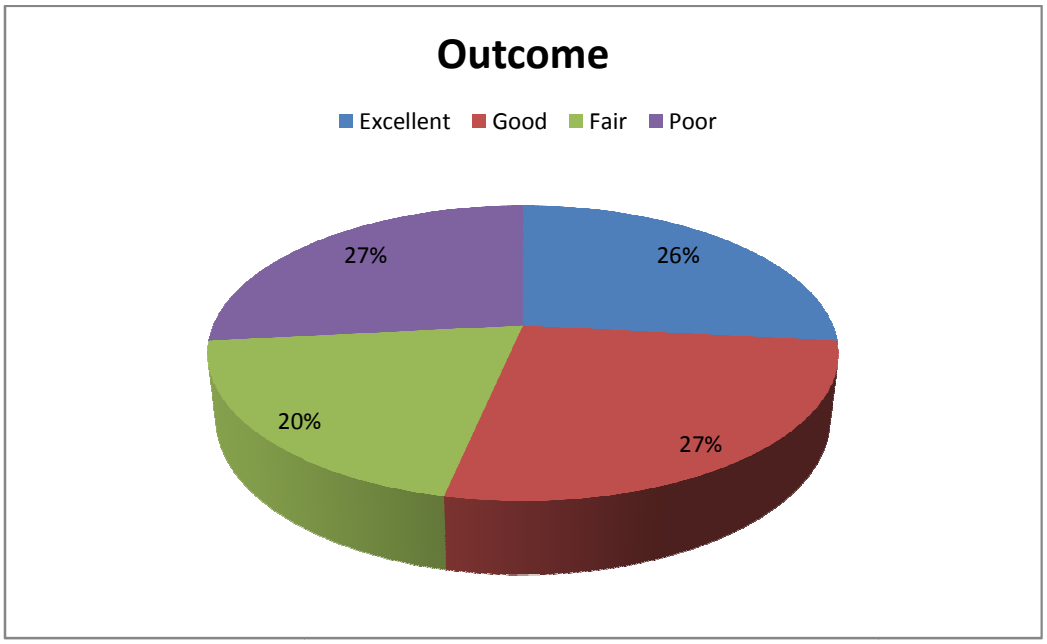
According to these criteria the bone result in our study was

Excellent - 8 cases

Good - 8cases

Fair - 6cases

Poor - 8 cases.



FUNCTIONAL RESULTS:

The functional results were assesses on the following five criteria:

1. A clinically detectable limp
2. Stiffness of the knee or ankle (i.e) more than 15 degrees loss of knee extension or more than 15 degrees of dorsiflexion of ankle compared to the normal limb.
3. Soft tissue reflex sympathetic dystrophy
4. Pain that reduces activity or disturbs sleep and
5. Loss of activity (unemployment or an inability to return to daily activities because of injury.)

Functional results– limp, equinus, ankle rigidity, soft tissue deformity, pain & inactivity

Excellent -active + no other

Good -active + 1 or 2

Fair - active + 3 or 4

Poor - inactive irrespective of whether other criteria were applicable.

According to these criteria the functional result was

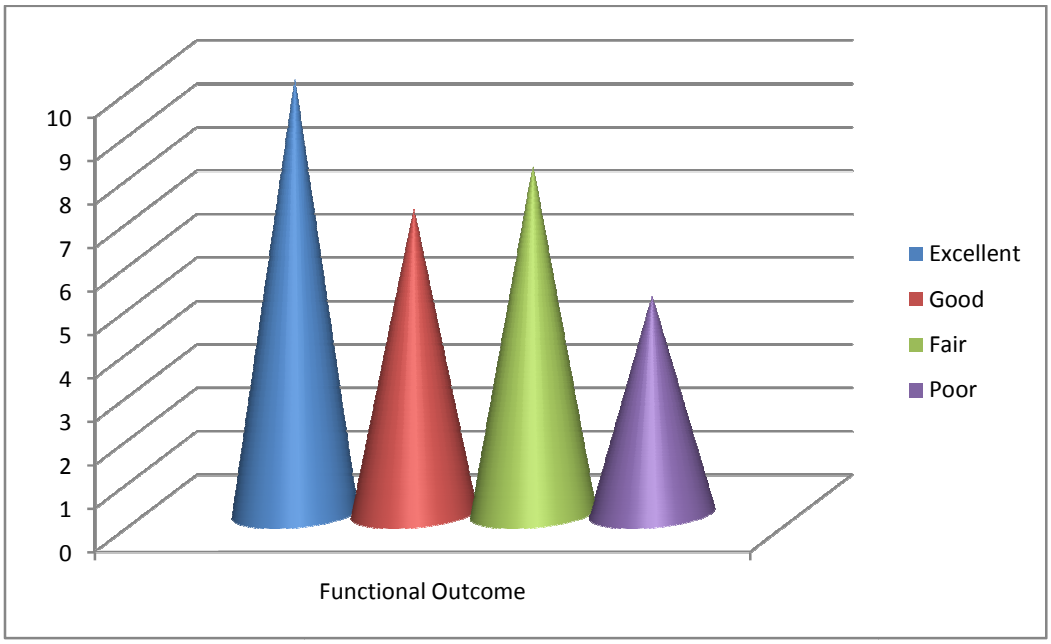
Excellent - 10 cases

Good - 7 cases

Fair - 8 cases

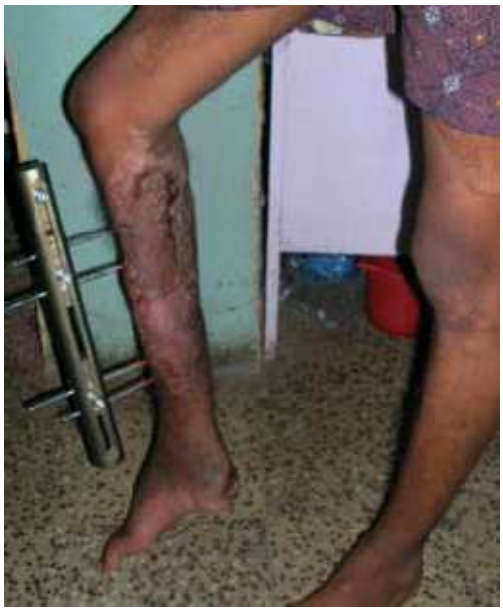
Poor - 5 cases.

The instrumentation did not cause any neurological or vascular injury.

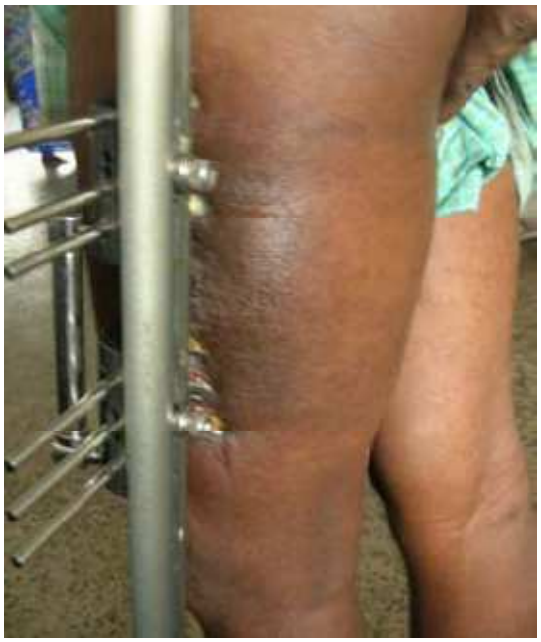

10
9
8
7
6
5
4
3
2
1
0
Functional Outcome
Excellent
Good
Fair
Poor

COMPLICATIONS

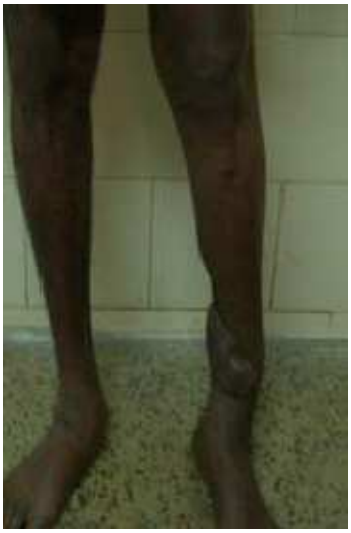
EQUINUS DEFORMITY AND KNEE STIFFNESS

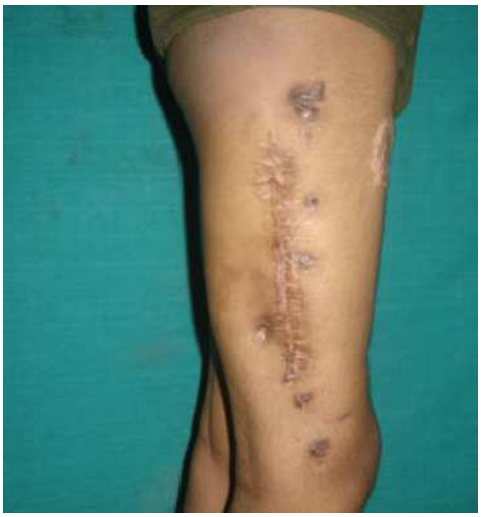


PIN TRACT INFECTION

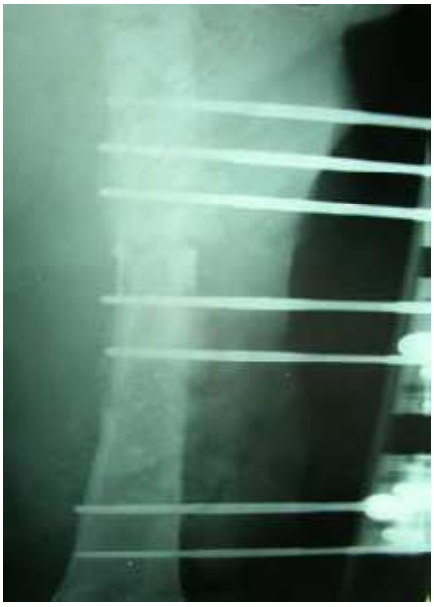


MALUNION **SHORTENING**





PERSISTENT INFECTION AND NON-UNION



We encountered certain complications and these complications were grouped into following categories as recommended by Paley.

(1) Problems –minor complications that were treated nonoperatively without anaesthesia.

(2) Obstacles -complications dealt with surgery

(3) True complications- were residual problemsafter the treatment period.

Problems:

 Superficial pin tract infection was found in 12 of the 30 cases (40%). All superficial pin tract infection responded to intravenous or oral antibiotics, except in two case where the infection persisted.

 Mild edema was frequently present and got resolved after removal of fixator except in 5 cases, which persisted even after removal of fixator, such patients were advised full weight bearing with elasto crepe bandage in the daytime and limb elevation in the nighttime for variable period of time.

Obstacles:

 During distraction in two cases metaphyseal pins got loosened which were readjusted in the operation theatre.

 Equinus correction was done by secondary surgical procedure like Achilles lengthening in 1 case.

 In two cases iliac bone grafting was done at the non-union site at the end of 4 months when there was insufficient evidence of bony union, to aid in union.

True complications:

 Malunion beyond the limits of acceptability occurred in 4 cases.

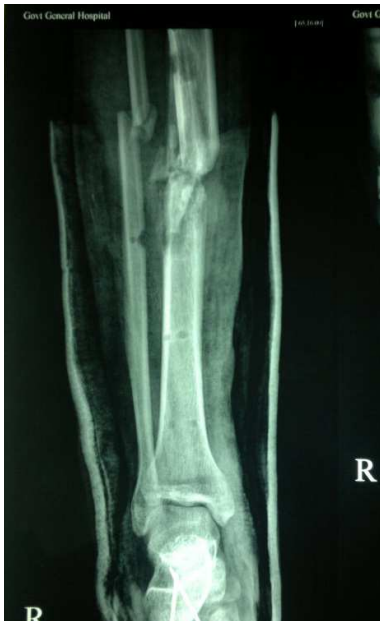
 Persisting nonunion of the ununited site occurred in three limbs.

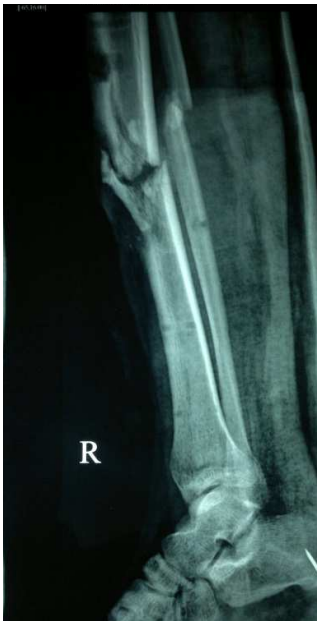
CASE ILLUSTRATIONS

Case I

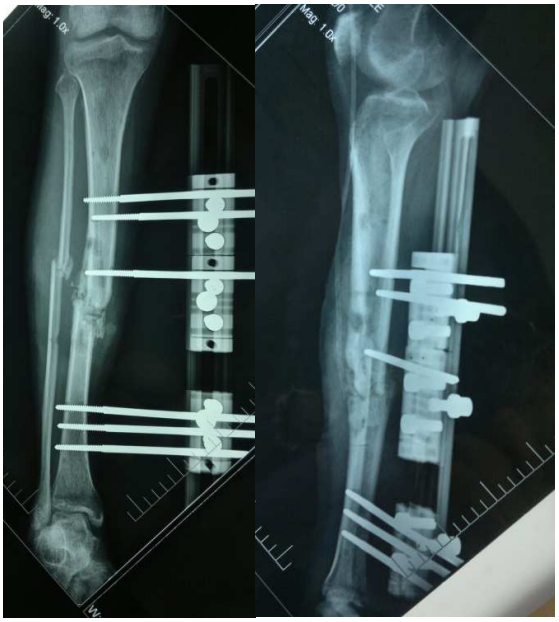
Rajesh, 24 yrs old male presented to us with infected nonunion of both bone fracture right leg, initially treated with external fixator and flap cover was done for the raw area over right leg.The external fixator was removed and the patient was on PTB cast,once the infection settled down we applied Limb reconstruction system for him in our institution with bone grafting taken from iliac crest .The non union site was excised and compression given at fracture site .after regular follow up the fracture was united by 6 months ,union obtained and the infection settled down.The fixator was removed and the patient was allowed to weight bear with PTB cast.

1. Infected non union right leg

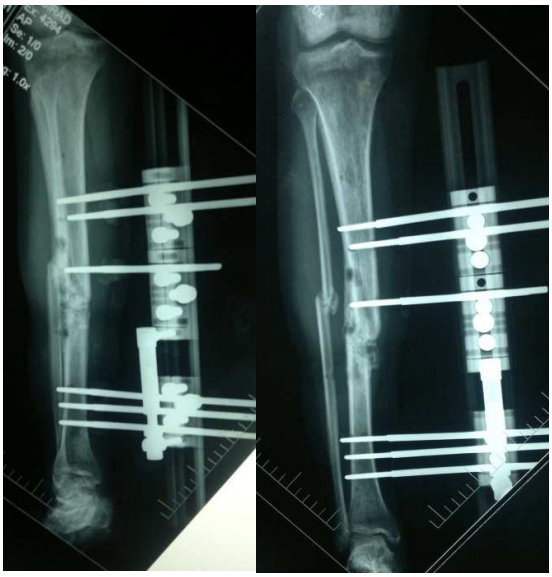




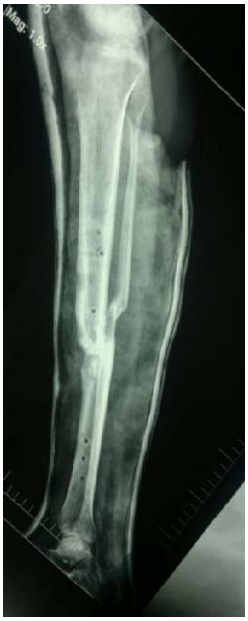
2. Debridement,LRSapplication,Bone grafting

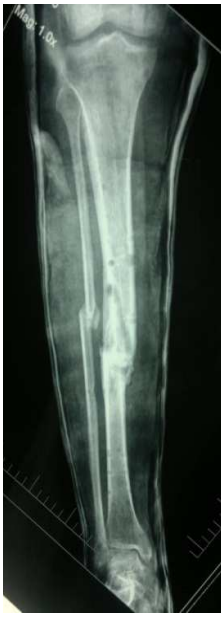


3.Four months follow up



4. Consolidation at 6 months , LRS removed, patient weight bears with PTB cast.

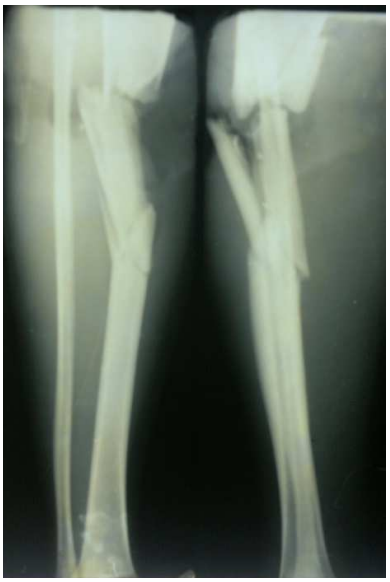




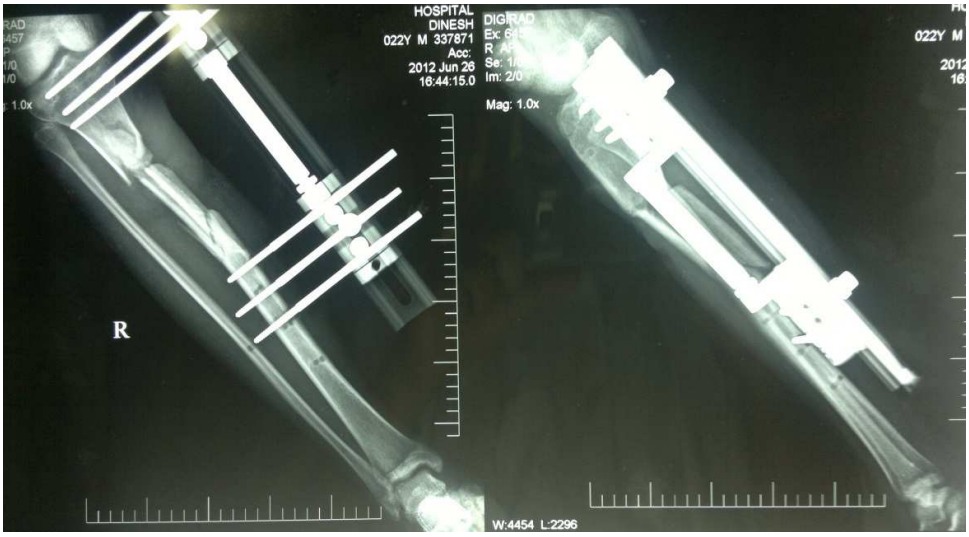
Case II

22 yr male ,Mr. Dinesh came with complaint of non union fracture both bone right leg,initially he was treated with external fixator for gradeIII B compound fracture both bone right leg, with raw area for which flap cover was done. External fixator was removed, limb reconstruction system was applied with compression at fracture site. With 6 months follow up, fracture was united,LRS removed and allowed weight bearing with PTB cast.

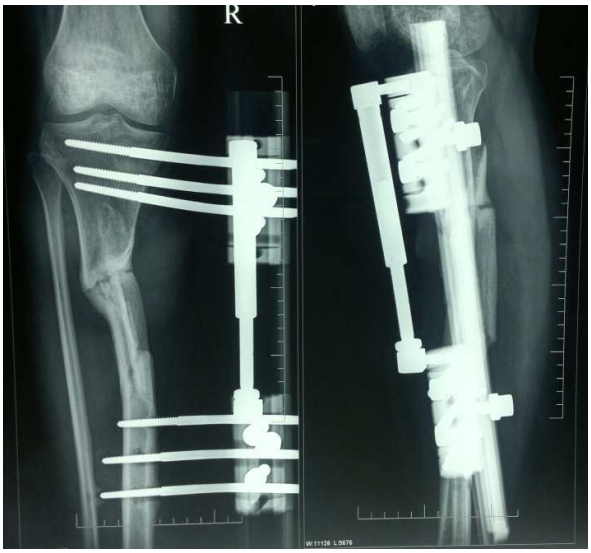
1. Non union both bones right leg



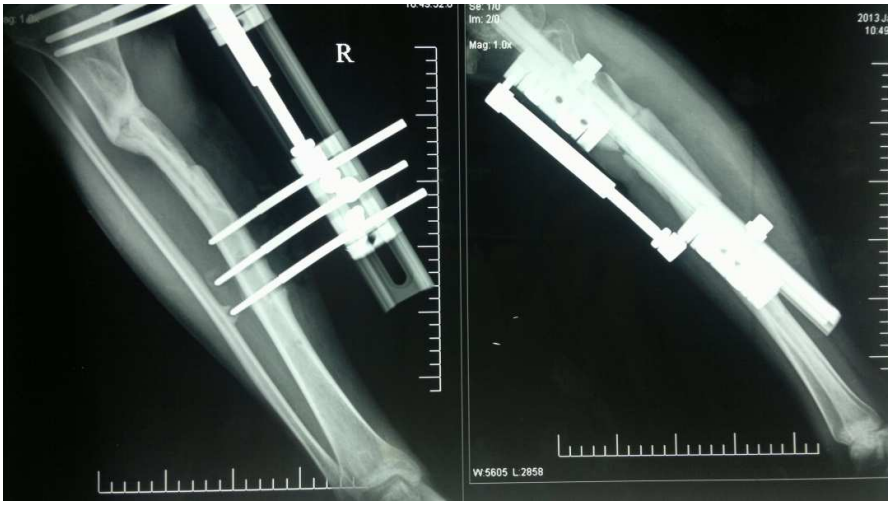
2. Debridement,LRS application



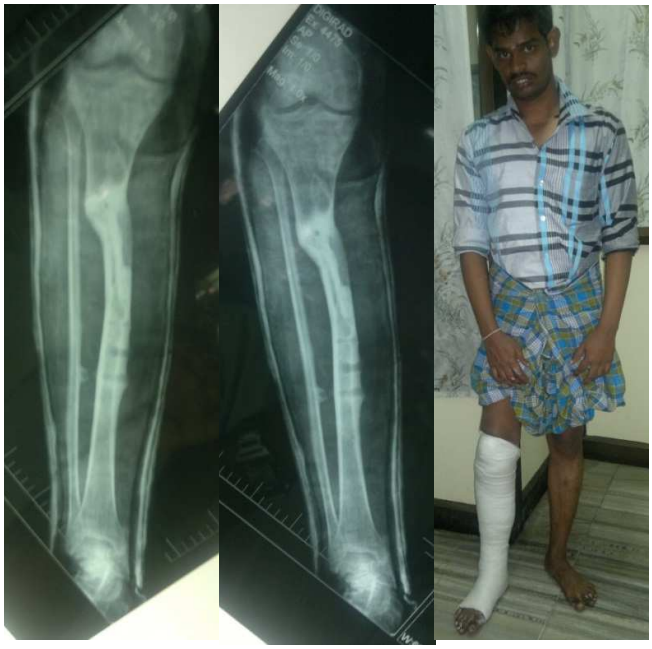
3. four months follow up



4. Six months follow up



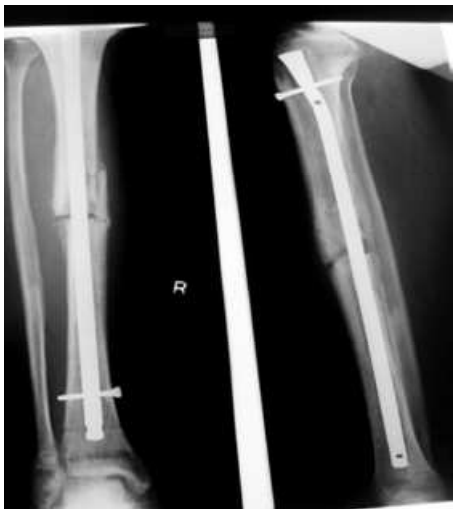
5. Consolidation at fracture site, patient allowed weight bearing with PTB cast.



Case III

GradeI compound fracture both bone right leg,initially treated with interlocking nail tibia which got infected with pus discharge.patient was treated with antibiotics according to pus culture and sensitivity .Implant exit ,through debridement of the infected bone, and Limb reconstruction system was applied with docking and corticotomy . Distraction started after seven days,0.25 mm four times a day for 30 days.callus seen on xray at regular follow up .at the end of 5 months consolidation seen on x ray and the Limb reconstruction system was removed .Patient allows weight bearing with PTB cast.

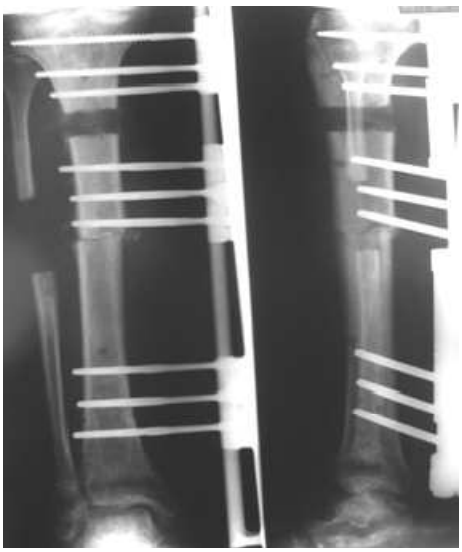
INFECTED NON-UNION



IMPLANT EXIT, DEBRIDEMENT, DOCKING,

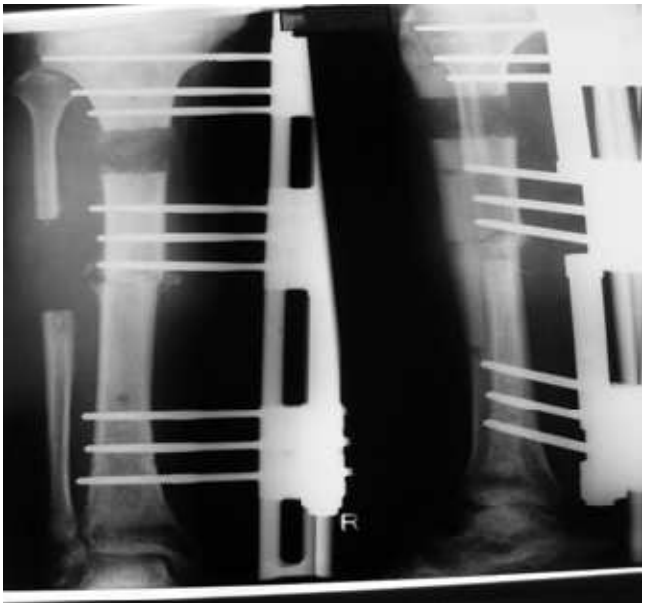
LRS APPLICATION, CORTICOTOMY,

DISTRACTION

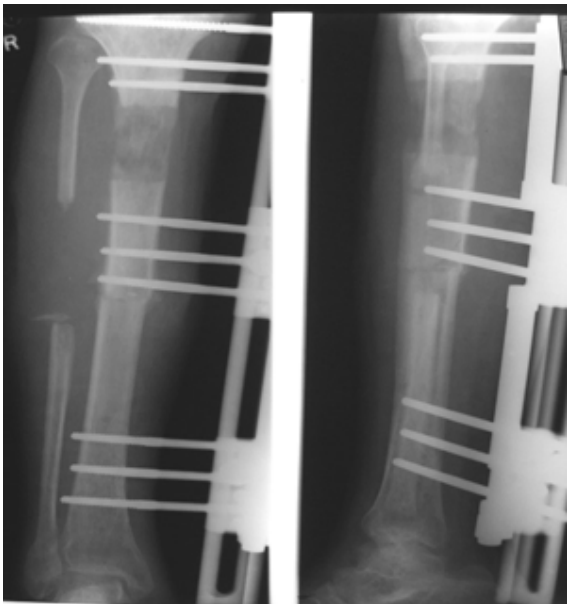


DURING DISTRACTION OSTEOGENESIS

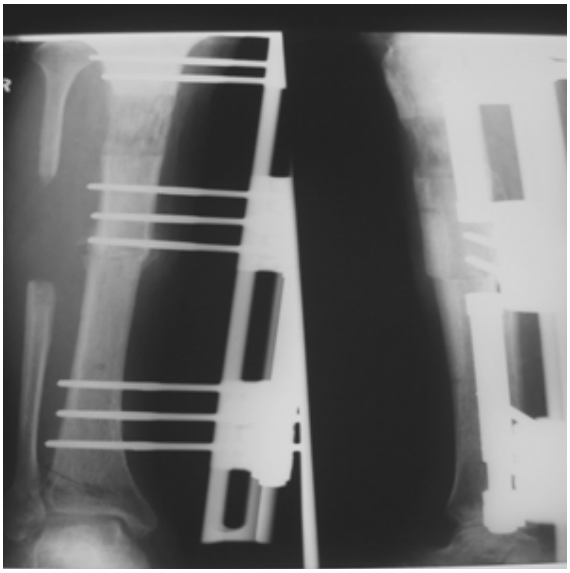
AT 4 WEEKS OF DISTRACTION



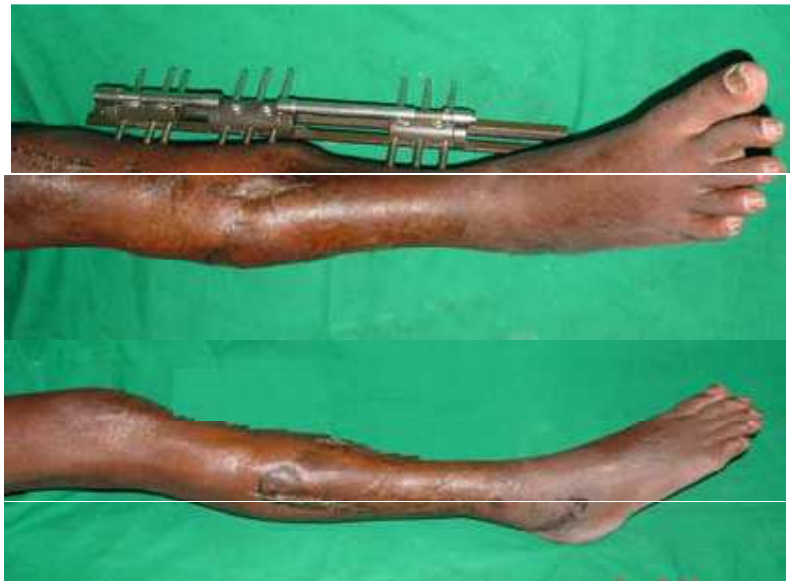
AT 8 WEEKS



GOOD CONSOLIDATION



LRS REMOVAL

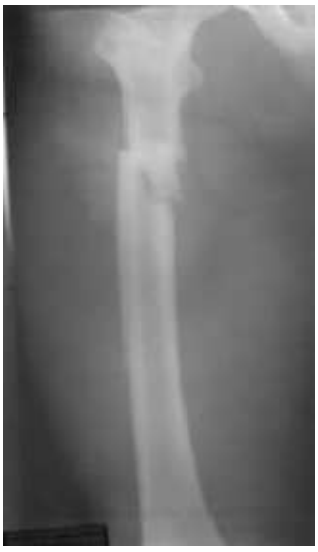


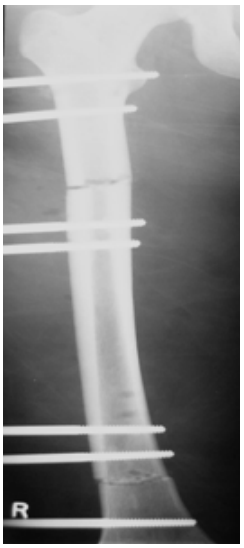
Case IV

29 years old male admitted with infected nonunion right femur ,initially it was compound fracture right femur which was treated with native bandage and got infected and presented with pus discharge and diffuse swelling over right lower limb which was diagnosed as Deep vein thrombosis and treated with Heparin. Infection was treated according to pus culture and sensitivity.Thorough debridement of nonunion site with Limb reconstruction system applied with acute docking and corticotomy.Distraction started after seven days ,0.25 mm four times per day for 30 days ,consolidation seen after 4 months in xray.

Infected non union

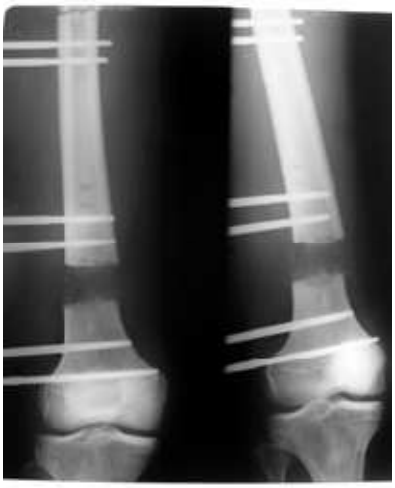
Debridement, Fixator applied, Corticotomy, Acute docking at fracture site,

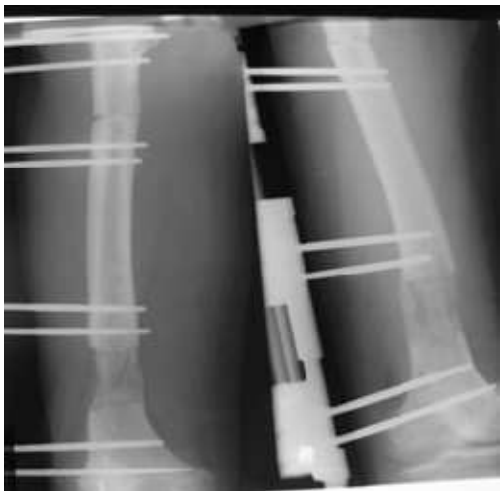




3 Weeks after distraction

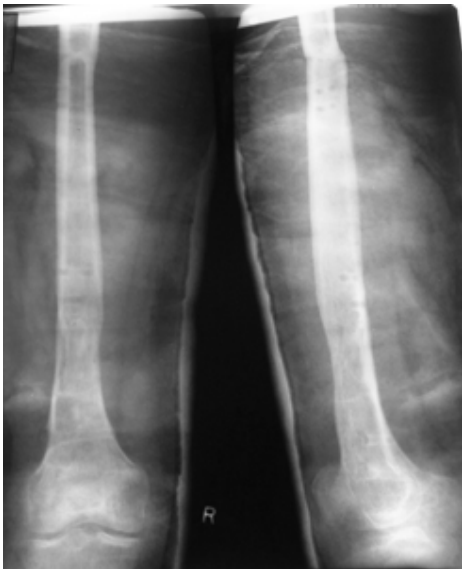
Consolidation after 4 months





Fixator in place:

After removal of fixator:



DISCUSSION

The goal of treating infected nonunion is to control the infection, healed aligned and drainage free limb which is functionally better than amputation and artificial prosthesis fitting.

Factors considered in reconstruction of long bone include

1.the patient's age,

2.metabolic status,

3. mobility of the foot and ankle,

4. Intact neuro-vascular structures and

5. Patient and attenders reassurance & rehabilitation. The bony debridement should be done upto punctate bleeding points observed. The non union site is resected and bony alignment achieved by compression at fracture site. The decision for reconstruction mainly depends upon

1. surgeon's ability to restore a functional limb ,
2. Duration of treatment ,
3. anticipated residual disability.

Thorough wound debridement and removal of nonviable bone and soft tissue is necessary for bony union to take place. Persistent infection

occurred in two patients for which ilizarov was applied, and in another patient repeat debridement, and corticotomy was planned for bone lengthening. The patient also must cooperate and understand their problems and the length of time the fixator has to be worn and their complications , for the treatment to be successful. The patient must be reassured preoperatively by teaching the treatment protocol.patient may accept their technique better in elective reconstruction rather then it is inflicted on them. Patients general health has to be improved by adequate nutrition, exercise, and encouragement to stop smoking. Distraction osteogenesis is associated with marked improvement of the blood supply, good vascularization is necessary to obtain bone healing, especially in patients with infected nonunion. Adequate preoperative planning necessary before surgery. As in other series functional results were inferior to bony results. An excellent bone result does not guarantee a good functional result. The nonunion site united in 24 out of 30 cases (80%), which is comparable to the study conducted by Eduardo Garcia et al16 in 2004 wherein the bony union result was 86.7%. Antonio Biasibetti in his study had a success rate of 93%. In long-term study of tibial fractures, Merchant and dietz 9 determined that angular deformities of 10 to 15 degrees are well tolerated. Leg length discrepancy of up to 2.5 cms does not require any treatment, 5to 6 degrees of tilt is acceptable. Likewise minimal translation in the mechanical axis is acceptable.

Pin tract infection occurred in 12 out of 30 cases (40%), which is comparable to the study conducted by Gopal.S et al20 , where the reported pin tract infection was in ten out of 19 cases (53%). In another study by J.R Coll the reported pin tract infection was 30%. Hence the rate of pin tract infection remained high in our study. Bone transport resulted in a better restoration of limb length discrepancy in lower limbs. Larger bone defects can be tackled with two level corticotomies. Our experience is only with single level corticotomy. Some of the patients who had shortening of more than 1 cm of lower limb did not give consent for limb lengthening procedure which was planned after evidence of union at the nonunion site. The mean limb length discrepancy noted in our study was 4 cm . In a study of 26 cases of infected nonunion conducted by Eduardo et al16. Bone grafts can be added, after infection settles at the nonunion site. Graft can also be added to theregenerate site if progression towards consolidation is slow as quoted in the literature[3]. The Limb reconstruction system is a telescopic device that can be locked for rigid fixation or unlocked to permit load sharing. Even though the cost of the fixator is high, the patients because of the following reasons accept it: Light weight, patient friendly, day to-day activities can be done easily, Since the pins are unilateral it is much more comfortable for the patients, hence joint mobilization can be done with ease. Being rigid[6], early weight bearing can be allowed with the device. Patient themselves can lengthen

very easily. More over plastic surgery procedures like cross leg flap, Fascio-cutaneous flap and skin grafting can be done comfortably. Once the patients have been taught about how to do distraction they are advised to come for review once in 15 days to asses the length gained and also to asses the quality of the regenerate. Moreover the fixator (other than the tapered half pins) can be reused for another patient provided there is no damage to the apparatus. The disadvantages include the high cost of the system, inability to use the apparatus for correction of infected nonunion with gross deformity, in severe osteoporosis, stabilization very close to a joint, for which Ilizarov fixator could be a better option. The cost factor has been reasonably managed by the introduction of Indian version of Limb reconstruction system . Compared with the Ilizarov ring fixator11 the LRS is simpler to apply and less cumbersome for the patients. The learning curve for application of the unilateral fixator is less steep than that encountered with that of an Ilizarov fixator.

CONCLUSION

In this study we conducted, we could achieve a success rate of 80%, giving good encouraging results to most of our patients. Hence we conclude that the Indian version of the Limb reconstruction system is effective and convenient method for the treatment of infected nonunion of long bones. This can also be used to correct the limb length discrepancies simultaneously, which can arise during the course of the treatment. Patient with poor cooperation are not good candidates for this technique, which requires wearing the frame for a long time, with probably additional secondary surgical procedure.

BIBLIOGRAPHY

1. A.S.A.M.I Group: operative principles of Ilizarov.1991. Pg 42-52
2. Ali F, Saleh M Injury. 2002 Mar; 33(2): 127-34
3. Biasibetti A, Aloj D: Mechanical and biological treatment of longbone nonunion: Injury.2005 Nov; 36 Suppl 4:S45-50.
4. Babulkar S, Pande K, Babulkar S. ClinOrthopRelat Res. 2005Feb;(431): 50-6-Non-union of Diaphysis of long bones
5. Behrens F, Searls K: External fixation of the tibia, Basic concepts JBone and Joint Surg Br. 1986 Mar; 68 (2): 246-54.
6. Chao EY, Hein TJ: Mechanical performance of the standard orthofixexternal fixator. Orthopedics 1988 Jul; 11 (7): 1057-69.
7. Chapman's orthopaedic surgery 3 rd edition; 2001:Chapter 26.
8. Chatziyiannakis AA, Nonunion of tibial fractures treated withexternal fixation. ActaOrthopScand Suppl. 1997 Oct; 275:77-9.
9. Charles T. Price: Unilateral fixators and mechanical axisrealignment. Orthopedic clinics of North America: vol.25.No.3.July1994.

10. Chantelot C, Robert G; Role of external fixators for the treatment ofhumeral fractures; report of 23 cases treated with orthofix externalfixators: Chir Main. 2002 Mar; 21 (2): 134-9

11. ChanchitSangkaew Injury.2005 Jan: 36(1): 185-93-Distractionosteogenesis using a conventional external fixator. A novel technique.

12. Chir Main. 2002 Mar; 21(2): 134-9-Role of External fixator in thetreatment of humeral fractures

13. Campbell's operative orthopaedics 10 th edition vol.3 pg. 2706-2714

14. DonnanLT, Saleh M, Rigby AS: JBJS Br. 2003 Mar; 85(2): 254-60.

15. Dendrinos G.K, S. Kontos Use of the Ilizarov technique fortreatment of nonunion of the tibia associated with infection. JBJS Vol 77-A, No. 6, June 1995.

16. Eduardo Garcia-Cimbrelo et al; Circular external fixation in tibialnonunions. Clinorthop. No.419, Feb 2004

17. Franco ML, Lodovico RB, Piergiulio: Bio mechanical factors indesigning screwsfor the Orthofix system Clinical Orthopaedics andrelated research No.308, pp 63-67: 1994

18. Guadrini G, Pascarella R, Colozza A, Stagni C:Infected nonunionof the humerus. ChirDegliOrgani Di Movi 85:251-255,2000

19. Guidera KJ, Hess WF, Highhouse KP, Ogden JA.Extremitylengthening: results and complications Pediatrorthop. 1991 Jan-Feb;11(1): 90-4.

20. Gopal .S, S.Majumder; The radical orthopaedic and plastic treatment of severe open fractures of the tibia: JBJS Vol 82-B, No.7 sep 2000.

21. Green SA, Moore TA, Spohn PJ: Orthopedics. 1988 Aug; 11 (8):1149-57.

22. Haidukewych.G.J, SperlingJ.W, Results of treatment of infectedHumeral Nonunions: The Mayo clinic experience. CORR No.414,pp.25-30, 2003

23. Hashmi MA, Ali A: Management of nonunion with monolateralexternal fixation. Injury. 2001 Dec; 32 Suppl 4:SD30-4.

24. Hessmann M, Mattens M, Use of unilateral external fixator infracture treatment: experience in 50 patients: Unfallchirurg.1994 Oct;97(10): 511-7.

25. Jain AK, Sinha S: Infected nonunion of long bones. CORR 2005Feb;(431): 57-65.

26. Kim NH, Hahn SB, The orthofix external fixator for the fracture oflong bones;Int. Orthop.1994 Feb; 18(1): 42-6

27. Kelly PJ: Infected nonunion of the femur and tibia. Orthopclin NorthAm. 1984 July; 15(3): 481-90.

28. Keating JF, Gardener E, Management of tibial fractures with theorthofix dynamic external fixator; J R CollSurg Edinb.1991 Aug;36(4): 267.

29. Lavini F, RenziBrivio L, Treatment of nonunion of the humerususing the orthofix fixator: Injury.2001 Dec; 32 Suppl 4:SD35-40

30. Melendez EM, Colon C: Clinical Orthopaedics and related research.Treatment of open tibial fractures with the orthofix fixator; 1989 Apr;No.241, pp.224-30.

31. Manual on the AO/ASIF tubular external fixator: 1985 edition.32.Mahaluxmivala J, Nadarajah R: Injury 2005 May; 36(5): 662-8.

33. Magyar G. Hydroxyapatite coating of threaded pins enhancesfixation JBJS Br. 1997 May; 79(3): 487-9.

34. Merchant T, Dietz F: Journal of bone and joint surgery71 [A]: 599-606,1989.

35. MuharremInan et al; Treatment of femoral nonunion by cycliccompression and distraction CORR No. 436,pp. 222-228, 2005.

36. Orthopaedics and related research: No.414, pp.25-30, 2003.

37. Ong CT, Choon DS, The treatment of open tibial fractures and oftibial nonunion with a novel external fixator:Injury.2002 Nov; 33(9):829-34.

38. Panagiotis M: Classification of nonunion. Injury. 2005 Nov; 36Suppl 4:S30-7.

39. Patzakis MJ, Results of bone grafting for infected tibial nonunion:CORR 1995 Jun;(315): 192-8.

40. L.J. Prokuski, J.L. Marsh The role of bone transport OCNA; Vol25:No.4: Oct. 1994.

41. Price CT, Mann JW.Experience with the orthofix device for limblengthening; Orthopclin North Am. 1991 Oct; 22(4): 651-61.

42. Ralston JL: J Orthop Trauma. 1990; 4(4): 449-57.

43. Rockwood and Green's 5th edition vol.1 pg.231-43

44. Ruedi T.P, W.M Murphy AO Principles of fracture management,2000.

45. Shaw DL, Lawton JO: Clinical results and cost effectiveness ofexternal fixation J R CollSurgEdinb. 1995 Oct; 40(5): 344-6.

46. TohCL, Jupiter JB: The infected nonunion of the tibia. ClinOrthopRelat Res. 1995 Jun;(315): 176-91.

47. Thomas P. Ruedi, William M. Murphy: AO principles of fracturemanagement; pg 765-77

48. Ueng SW, Wei FC, Shih CH: Management of femoral diaphysealinfected nonunion J Trauma. 1999 Jan; 46(1): 97-103.

49. Websites- www.othofix.com, www.pubmed.com, www.jbjs.org

50. Zachee B, Roosen P: The dynamic axial fixator in fractures of thetibia and femur. A retrospective study in 98 patients: Actaorthop.Belg.1991; 57(3): 266-71.

PROFORMA

Name	IP No.
Age	Date of admission
Sex	Date of discharge
Occupation	Date of surgery
Address	

I. Chief complaints

a) Deformity

b) Inability to use the limb

c) Pus discharge from the limb

d) Shortening of the limb

II. History of present complaints

a) Date of trauma

b) Nature of trauma

c) Other associated complaints

III. Past medical history

a) Number of previous procedures

b) Type of previous procedures

c) Systemic disorders

IV. General physical examination

a) Built and nutrition

b) BP

c) Pulse

d) Temperature

e) Pallor

f) Icterus

g) Cyanosis

h) Clubbing

i) Generalized lymphadenopathy

V. Systemic examination

a) CVS

b) RS

c) Abdomen

d) CNS

VI. Local examination

a) Bone involved

b) Deformity

c) Condition of skin

d) Infection at nonunion site

e) Range of motion of adjacent joints

f) Shortening of the limb

VII. Investigation

a) X-ray of affected limb- AP & Lateral views

I) Site of non-union

II) Signs of infection

III) Bone defect

IV) Deformity

b) Blood investigations

c) Urine examination

d) ECG

e) Chest X-ray

f) Pus for culture and sensitivity

VIII. Treatment details

a) Date of application of LRS

b) Bone grafting

c) Other secondary procedures

IX. **Follow-up protocol**

(A) Clinical

S.No.	Clinical findings	6weeks	12weeks	24 weeks	Completion of treatment
i)	Abnormal mobility at fracture site				
ii)	Joint movements				
iii)	Activities of patient				
iv)	Loosening of LRS pins				
v)	Pin track infection				
vi)	Visible deformity				
vii)	Local skin condition				
Viii)	Neurovascular examination				

(B) Radiological

S.No.	Radiological findings	6weeks	12weeks	24 weeks	Completion of treatment
i)	Gap at fracture site				
ii)	Callus formation				
iii)	Regenerate (in patients where distraction osteogenesis is carried out)				
iv)	Features of osteomyelitis				
	a) At fracture site				
	b) At pin track				
v)	Deformities				

INFORMATION TO PARTICIPANT

Principal Investigator :

Co-investigator :

Name of the Participant :

Title

Prospective and retrospective study of non-union long bone fracture treated by LRS (limb reconstruction system), outcome analysis

You are invited to take part in this study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You are being asked to participate in this study being conducted in OPD, Institute of Orthopaedics & Traumatology, Rajiv Gandhi Government General Hospital, Chennai-600 003.

Sample size 30. Patients with non union long bones are selected, they are treated with LRS (Limb Reconstruction System) with bone grafting (or) Bone transport (or) docking and compression. They are followed up at regular intervals and bone union is checked by X-Rays at schedule visits at 4,8,12 weeks after your initial visit. You will be required to visit the hospital 4 number of times during the study.

At each visit, the study physician will examine you. X-rays will be carried out at each visit.

You may have to come to hospital for examination & investigation apart from your schedule visits, if required.

The result of the research may provide benefits to the society in terms of advancement of medical knowledge and or therapeutic benefits to future patients.

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examination, investigations, and your medical history). By signing this document, you will be allowing the research team investigators other study personal, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

Your decision to not participate in this research study will not affect your medical care or your relationship with investigator or the institution. Your doctor will still take care of you and you will not loose any benefits to which you are entitled.

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it advisable that you talk to the research team prior to stopping the treatment.

Signature of Investigator **Signature of Participant**

PATIENT CONSENT FORM

STUDY TITLE: A study on functional outcome of nonunion long bone fractures treated with Limb reconstruction system

STUDY CENTRE: Institute of Orthopaedics and Traumatology
Rajiv Gandhi Govt. General Hospital and Madras Medical College
Chennai-3

Patient's Name :_____

Patient's Age :_____

Identification Number :_____

I confirm that I have understood the purpose and procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.

I understand that the sponsor of the clinical study, others working on the sponsor's behalf, the ethics committee and the regulatory authorities will not need my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arose from this study.

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully Co-operate with the study team, and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study of " **A study on functional outcome of nonunion long bone fractures treatment by limb reconstruction system**
"

I hereby give permission to undergo complete clinical examination, and diagnostic tests including hematological, biochemical, radiological urine examination.

Signature / Thumb impression _____Place _____Date _____

Of the patient.

Patient's Name & Address: _____

_____

Signature of the Investigator: _____ Place _____Date _____

Study Investigator's Name: _____